

2/26/01 2:18 pm

Notification Tracking Sheet

=====
Bp number: 01-053-07n
=====

App number: 2001-411XRAB
Received: 2/22/01
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/24/01
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 3/23/01
End movement: 3/23/02
Begin release: 3/23/01
End release: 3/23/02
Acre: 2.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--|----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>ajd</i>] | [2/27/01] |
| 2. <input type="checkbox"/> Review by biotechnologist | [<i>CR</i>]* | [2-27-01]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KLR</i>] | [3/6/01]* |
| 4. <input type="checkbox"/> State response | | |

- | | O/d | Loc | Site | Reg | | |
|------------|--------|-----|------|------|---|-----|
| Interstate | *Dest* | CO | * | *WR | * | [] |
| Interstate | *Orig* | CO | * | *WR | * | [] |
| Release | * | *CO | * | 1*WR | * | [] |
-
- | | | |
|--|----------------|-------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>all</i>] | [3/1/01] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KLR</i>] | [3/7/01]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KLR</i>] | [3/7/01] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify | | |

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-411XRAB

February 21, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-053-07n

1. USDA Reference Number

2. Applicant Reference Number 2001-411XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 23, 2001 - March 23, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite and elite lines.

CONFIDENTIAL

Monsanto Reference ID

2001-411XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2001-411XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 2000 kg. wheat seed to and from each location.

ORIGIN:

CO

DESTINATION:

CO

Ship From:

CO

*[(b) (4) Larimer County/Province, CO, (b) (4)
U.S.A

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO,
(b) (4), (b) (6), (b) (7)(C) U.S.A,
] - CBI

*[(b) (4) Rio Grande County/Province, CO,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO,
(b) (4), (b) (6), (b) (7)(C) U.S.A,
Comments: (b) (4), (b) (6), (b) (7)(C)] - CBI

Ship To:

CO

*[(b) (4) Larimer County/Province, CO, (b) (4)
U.S.A

CONFIDENTIAL

Monsanto Reference ID
2001-411XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO,
(b) (4), (b) (6), (b) (7)(C) U.S.A

] - CBI

*r (b) (4) Rio Grande County/Province, CO,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO,
(b) (4), (b) (6), (b) (7)(C) U.S.A

Comments: local contact Merlin Dillon] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-411XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

CO (1)

CO

[REDACTED] (b) (4) Rio Grande County/Province, CO, USA,
2 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
[REDACTED] (b) (4), (b) (6), (b) (7)(C) CO, [REDACTED] (b) (4), (b) (6), (b) (7)(C) U.S.A., [REDACTED] (b) (4), (b) (6), (b) (7)(C)

Comments: [REDACTED] (b) (4), (b) (6), (b) (7)(C)] - CBI

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CHESTERFIELD, MISSOURI 63198

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<http://www.monsanto.com>

CONFIDENTIAL

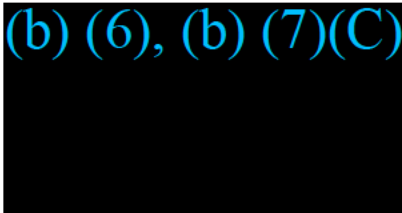
Monsanto Reference ID

2001-411XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 21, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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700 CHESTERFIELD PKWY NORTH
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FAX (636) 737-7085

<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-411XRAB

February 21, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-053-07n

1. USDA Reference Number

2. Applicant Reference Number 2001-411XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 23, 2001 - March 23, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite and elite lines.

CBI-DELETED

Monsanto Reference ID

2001-411XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-411XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 2000 kg. wheat seed to and from each location.

ORIGIN:

CO

DESTINATION:

CO

Ship From:

CO

[CBI Deleted] -- *Larimer County/Province, CO, U.S.A

[CBI Deleted] -- *Rio Grande County/Province, CO, USA

Ship To:

CO

[CBI Deleted] -- *Larimer County/Province, CO, U.S.A

CBI-DELETED

Monsanto Reference ID
2001-411XRAB

[CBI Deleted] -- *Rio Grande County/Province, CO, USA

CBI-DELETED

Monsanto Reference ID

2001-411XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CO (1)

CO

[CBI Deleted] -- Rio Grande County/Province, CO, USA, 2 acres

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CBI-DELETED

Monsanto Reference ID

2001-411XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 21, 2001

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CBI-DELETED

Monsanto Reference ID

2001-411XRAB

Permit Unit

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4700 River Rd.

Riverdale, MD 27037

01-053-07n

February 21, 2001

1. USDA Reference Number

2. Applicant Reference Number 2001-411XRAB

3. Applicant/Responsible Party

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Phone

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FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 23, 2001 - March 23, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite and elite lines.

CBI-DELETED

Monsanto Reference ID

2001-411XRAB

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33391

Constructs: PV-TXGT10

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Promoter: CMOVa/I2 -- [CBI Deleted]

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CBI-DELETED

Monsanto Reference ID

2001-411XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 2000 kg. wheat seed to and from each location.

ORIGIN:

CO

DESTINATION:

CO

Ship From:

CO

[CBI Deleted] -- *Larimer County/Province, CO, U.S.A

[CBI Deleted] -- *Rio Grande County/Province, CO, USA

Ship To:

CO

[CBI Deleted] -- *Larimer County/Province, CO, U.S.A

CBI-DELETED

Monsanto Reference ID
2001-411XRAB

[CBI Deleted] -- *Rio Grande County/Province, CO, USA

CBI-DELETED

Monsanto Reference ID

2001-411XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CO (1)

CO

[CBI Deleted] -- Rio Grande County/Province, CO, USA, 2 acres

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CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

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~~CBI-DELETED~~

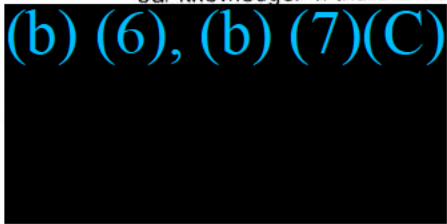
Monsanto Reference ID

2001-411XRAB

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(b) (6), (b) (7)(C)



Monsanto Company

February 21, 2001

file copy

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

February 27, 2001

Dear Mr. Yergert:

Enclosed is notification 01-053-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-053-07n	Applicant #:	2001-411XRAB
Received:	February 22, 2001	Effective:	March 24, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO		
Release destination:	CO		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151
Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008396



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

February 26, 2001

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

Dear Mr. Yergert:

Enclosed is notification 01-053-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-053-07n	Applicant #:	2001-411XRAB
Received:	February 22, 2001	Effective:	March 24, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO		
Release destination:	CO		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: MITCHELL YERGERT

Signature: (b) (6), (b) (7)(C)

Date: MARCH 7, 2001

State: COLORADO

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_008397

MAR 7 2001

March 7, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and **may be executed according to 7 CFR 340.3(c), effective on or after March 24, 2001.**

Interstate movement and Release
Notification no. 01-053-07n (2001-411XRAB)
Regulated article - Wheat
Destination - Colorado

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official and the Regional Program Manager (Biotechnology).

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:
M. Yergert, Colorado Dept. of Agric., Lakewood, CO
R. Stoaks, PPQ, SCR, WR, Sacramento, CA
File number 01-053-07n

OR120018_BR_008398

FAX COVER PAGE*File*Total Pages with cover 1

Date: Oct 2, 2000

Fax to: (b) (6), (b) (7)(C), (b) (4)

Monsanto

700 Chesterfield Parkway North

St. Louis, MO

From: Ralph Stoaks

USDA, APHIS, PPQ, WR

Regional Program Manager (Biotechnology/Biological Control)

1629 Blue Spruce Dr.

Ft. Collins, CO 80524

My telephone: (b) (6), (b) (7)(C), (b) (4)

My Fax: (970) 494-0408

Business Hours 7 am to 3: 30 pm Mt. Time

Comments: This fax is a record to confirm that PPO Officer Tiffany Weir and PPQ Technician Laura Polis met with (b) (6), (b) (7)(C), (b) (4) on September 21, 2001. They collected 11 bags of wheat seed from the test plot of 01-053-07N including the non-transgenic Durum and South Dakota varieties.

The wheat was transported to Denver and burned on September 21, 2001 in the afternoon in the incinerator located at the Denver International Airport.

This concludes the case on the transgenic wheat trial.

*Qu**NAR**10/3/01*

FAX COVER PAGE**Total Pages with cover** 2**Date:** October 3/01**Fax to:** Deborah Knott at fax: (301) 734-⁸⁷~~7800~~

Branch Chief, PPQ Permits

USDA, APHIS

Riverdale, MD

James White at fax: (301) 734-8669

Senior Biotechnologist

USDA, APHIS, PPQ, SS

Riverdale, MD

From: Ralph Stoaks

USDA, APHIS, PPQ, WR

Regional Program Manager (Biotechnology/Biological Control)

1629 Blue Spruce Dr.

Ft. Collins, CO 80524

My telephone: (970) 494-2532**My Fax:** (970) 494-0408

Business Hours 7 am to 3: 30 pm Mt. Time

Comments: See attached fax to Monsanto regarding disposition of 01-053-07N seed destruction.

CONFIDENTIAL

2001 Wheat Field Test Report
USDA #01-053-07n Monsanto #2001-411XRAB

October 16, 2002

Biotech Field Compliance Team
Monsanto Company

Location
2147308798

County
Rio Grande County

State
CO

Rio Grande County/CO (2147308798)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, they are entitled to the same protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

**2001 Wheat Field Test Report
USDA #01-053-07n Monsanto #2001-411XRAB**

October 16, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147308798	Rio Grande County	CO

Rio Grande County/CO (2147308798)

Planting Date: 05/16/2001

Harvest Date: 09/18/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

=====

Bp number: 01-053-09n

=====

App number: 2001-416XRAB
 Received: 2/22/01
 Institution: Monsanto
 Recipient: Wheat
 Status: Pending
 Effective date: 3/24/01
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: (b) (6), (b) (7)(C)
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[<i>ajd</i>]	[2/27/01]
2. <input type="checkbox"/> Review by biotechnologist	[<i>CRR</i>]*	[2-27-01]*
3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i>	[<i>KdN</i>]	[3/5/01]*
4. <input type="checkbox"/> State response		

O/d	Loc	Site	Reg		
Interstate	*Dest*	MN	*	*NER	*
Interstate	*Dest*	MO	*	*SCR	*
Interstate	*Dest*	ND	*	*SCR	*
Interstate	*Dest*	SD	*	*SCR	*
Interstate	*Orig*	MN	*	*NER	*
Interstate	*Orig*	MO	*	*SCR	*
Interstate	*Orig*	ND	*	*SCR	*
Interstate	*Orig*	SD	*	*SCR	*
Release	*	*MN	*	3*NER	*
Release	*	*ND	*	2*SCR	*
Release	*	*SD	*	2*SCR	*

5. <input checked="" type="checkbox"/> Enter genes into database	[<i>all</i>]	[3/1/01]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw	[<i>KdN</i>]	[4/23/01]*
7. <input checked="" type="checkbox"/> Enter final data into database	[<i>KdN</i>]	[4/25/01]
8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

Reason for tardiness: (MN) responded on 4/23/2001.

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-416XRAB

February 21, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-053-09n

1. USDA Reference Number

2. Applicant Reference Number 2001-416XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 23, 2001 - March 23, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate Tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite and elite lines.

CONFIDENTIAL

Monsanto Reference ID

2001-416XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID

2001-416XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 2000 kg. of wheat seed to and from each location.

ORIGIN:

MN, MO, ND, SD

DESTINATION:

MN, MO, ND, SD

Ship From:

MN

*[(b) (4)] Polk County/Province,
MN, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)
] - CBI

*[(b) (4)] Ramsey County/Province, MN,
55108, U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)
] - CBI

*[(b) (4)] Dakota
County/Province, MN, (b) (4) U.S.A.

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Monsanto Reference ID
2001-416XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) U.S.A.
]- CBI

*[(b) (4) (b) (4) Stevens County/Province, MN,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)
MN, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)
]- CBI

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C) MO,
]- CBI

ND

*[(b) (4) McHenry County/Province, ND, (b) (4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA,
]- CBI

*[(b) (4), (b) (6), (b) (7)(C) McHenry County/Province, ND, USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA,
]- CBI

CONFIDENTIAL

Monsanto Reference ID
2001-416XRAB

* (b) (4) Cass County/Province, ND, (b) (4) U.S.A
CONTACT: (b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C)
] - CBI

* (b) (4) Cass County/Province, ND, (b) (4)
CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C)
] - CBI

SD

* (b) (4) Codington County/Province, SD, (b) (4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)
] - CBI

* (b) (4) (b) (4) Brookings County/Province, SD,
(b) (4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)
] - CBI

* (b) (4) Brookings County/Province, SD, (b) (4)
USA

CONFIDENTIAL

Monsanto Reference ID

2001-416XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) SD (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

Ship To:

MN

*[(b) (4)] Polk County/Province,
MN (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4)] Ramsey County/Province, MN,
(b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)

MN (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4)] Dakota
County/Province, MN (b) (4) U.S.A.

CONFIDENTIAL

Monsanto Reference ID
2001-416XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN (b) (4), (b) (6), (b) (7)(C) U.S.A.

] - CBI

*(b) (4) (b) (4) Stevens County/Province, MN,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
MN, (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO
*[(b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

ND
*[(b) (4) McHenry County/Province, ND (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID
2001-416XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

*(b) (4), (b) (6), (b) (7)(C) McHenry County/Province, ND, USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

*(b) (4) Cass County/Province, ND, (b) (4) U.S.A

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*(b) (4) Fargo, Cass County/Province, ND, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C)

] - CBI

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Monsanto Reference ID
2001-416XRAB

SD

*[(b) (4) Codington County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Brookings County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Brookings County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-416XRAB

CONFIDENTIAL

Monsanto Reference ID

2001-416XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (3), ND (2), SD (2)

MN

[(b) (4)] Polk County/Province, MN,
USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

[(b) (4)] Dakota
County/Province, MN, U.S.A., 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) U.S.A.

] - CBI

[(b) (4)] Stevens County/Province, MN, USA,
2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-416XRAB

ND

[(b) (4), (b) (6), (b) (7)(C) McHenry County/Province, ND, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER:
(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

[(b) (4) Cass County/Province, ND, U.S.A, 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C)

] - CBI

SD

(b) (4) Codington County/Province, SD, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4) Brookings County/Province, SD, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO

Food • Health • Hope



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-416XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 21, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-416XRAB

February 21, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-053-09n

1. USDA Reference Number

2. Applicant Reference Number 2001-416XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EEmail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 23, 2001 - March 23, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate Tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite and elite lines.

CBI-DELETED

Monsanto Reference ID

2001-416XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-416XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 2000 kg. of wheat seed to and from each location.

ORIGIN:

MN, MO, ND, SD

DESTINATION:

MN, MO, ND, SD

Ship From:

MN

[CBI Deleted] -- *Polk County/Province, MN, USA

[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.

[CBI Deleted] -- *Dakota County/Province, MN, U.S.A.

CBI-DELETED

Monsanto Reference ID
2001-416XRAB

[CBI Deleted] -- *Stevens County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

ND

[CBI Deleted] -- *McHenry County/Province, ND, USA

[CBI Deleted] -- *McHenry County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, U.S.A

CBI-DELETED

Monsanto Reference ID
2001-416XRAB

[CBI Deleted] -- *Cass County/Province, ND

SD

[CBI Deleted] -- *Codington County/Province, SD, USA

[CBI Deleted] -- *Brookings County/Province, SD, USA

[CBI Deleted] -- *Brookings County/Province, SD, USA

Ship To:

MN

[CBI Deleted] -- *Polk County/Province, MN, USA

CBI-DELETED

Monsanto Reference ID
2001-416XRAB

[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.

[CBI Deleted] -- *Dakota County/Province, MN, U.S.A.

[CBI Deleted] -- *Stevens County/Province, MN, USA

CBI-DELETED

Monsanto Reference ID

2001-416XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

ND

[CBI Deleted] -- *McHenry County/Province, ND, USA

[CBI Deleted] -- *McHenry County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, U.S.A

CBI-DELETED

Monsanto Reference ID
2001-416XRAB

[CBI Deleted] -- *Cass County/Province, ND

SD

[CBI Deleted] -- *Codington County/Province, SD, USA

[CBI Deleted] -- *Brookings County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID
2001-416XRAB

[CBI Deleted] -- *Brookings County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID

2001-416XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (3), ND (2), SD (2)

MN

[CBI Deleted] -- Polk County/Province, MN, USA, 2 acres

[CBI Deleted] -- Dakota County/Province, MN, U.S.A., 2 acres

[CBI Deleted] -- Stevens County/Province, MN, USA, 2 acres

ND

[CBI Deleted] -- McHenry County/Province, ND, USA, 2 acres

CBI-DELETED

Monsanto Reference ID
2001-416XRAB

[CBI Deleted] -- Cass County/Province, ND, U.S.A, 2 acres

SD

[CBI Deleted] -- Codington County/Province, SD, USA, 2 acres

[CBI Deleted] -- Brookings County/Province, SD, USA, 2 acres

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CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-416XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 21, 2001

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Monsanto Reference ID

2001-416XRAB

Permit Unit

February 21, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-053-09n

1. USDA Reference Number

2. Applicant Reference Number 2001-416XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 23, 2001 - March 23, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate Tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite and elite lines.

CBI-DELETED

Monsanto Reference ID

2001-416XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

none

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

none

CBI-DELETED

Monsanto Reference ID

2001-416XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 2000 kg. of wheat seed to and from each location.

ORIGIN:

MN, MO, ND, SD

DESTINATION:

MN, MO, ND, SD

Ship From:

MN

[CBI Deleted] -- *Polk County/Province, MN, USA

[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.

[CBI Deleted] -- *Dakota County/Province, MN, U.S.A.

CBI-DELETED

Monsanto Reference ID
2001-416XRAB

[CBI Deleted] -- *Stevens County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

ND

[CBI Deleted] -- *McHenry County/Province, ND, USA

[CBI Deleted] -- *McHenry County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, U.S.A

CBI-DELETED

Monsanto Reference ID
2001-416XRAB

[CBI Deleted] -- *Cass County/Province, ND

SD

[CBI Deleted] -- *Codington County/Province, SD, USA

[CBI Deleted] -- *Brookings County/Province, SD, USA

[CBI Deleted] -- *Brookings County/Province, SD, USA

Ship To:

MN

[CBI Deleted] -- *Polk County/Province, MN, USA

CBI-DELETED

Monsanto Reference ID
2001-416XRAB

[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.

[CBI Deleted] -- *Dakota County/Province, MN, U.S.A.

[CBI Deleted] -- *Stevens County/Province, MN, USA

CBI-DELETED

Monsanto Reference ID

2001-416XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

ND

[CBI Deleted] -- *McHenry County/Province, ND, USA

[CBI Deleted] -- *McHenry County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, U.S.A

CBI-DELETED

Monsanto Reference ID
2001-416XRAB

[CBI Deleted] -- *Cass County/Province, ND

SD

[CBI Deleted] -- *Codington County/Province, SD, USA

[CBI Deleted] -- *Brookings County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID
2001-416XRAB

[CBI Deleted] -- *Brookings County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID

2001-416XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (3), ND (2), SD (2)

MN

[CBI Deleted] -- Polk County/Province, MN, USA, 2 acres

[CBI Deleted] -- Dakota County/Province, MN, U.S.A., 2 acres

[CBI Deleted] -- Stevens County/Province, MN, USA, 2 acres

ND

[CBI Deleted] -- McHenry County/Province, ND, USA, 2 acres

CBI-DELETED

Monsanto Reference ID
2001-416XRAB

[CBI Deleted] -- Cass County/Province, ND, U.S.A, 2 acres

SD

[CBI Deleted] -- Codington County/Province, SD, USA, 2 acres

[CBI Deleted] -- Brookings County/Province, SD, USA, 2 acres

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FAX (636) 737-7085

<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-416XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 21, 2001

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

February 27, 2001

Dear Dr. Hanks:

Enclosed is notification 01-053-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-053-09n	Applicant #:	2001-416XRAB
Received:	February 22, 2001	Effective:	March 24, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO ND SD		
Release destination:	MN ND SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008448

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 27, 2001

Dear Mr. Brown:

Enclosed is notification 01-053-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-053-09n	Applicant #:	2001-416XRAB
Received:	February 22, 2001	Effective:	March 24, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO ND SD		
Release destination:	MN ND SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

JS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008449

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 27, 2001

Dear Mr. Nelson:

Enclosed is notification 01-053-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-053-09n	Applicant #:	2001-416XRAB
Received:	February 22, 2001	Effective:	March 24, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO ND SD		
Release destination:	MN ND SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(S)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008450

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 27, 2001

Dear Mr. Fridley:

Enclosed is notification 01-053-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-053-09n	Applicant #:	2001-416XRAB
Received:	February 22, 2001	Effective:	March 24, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO ND SD		
Release destination:	MN ND SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008451



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

February 26, 2001

Dear Dr. Hanks:

Enclosed is notification 01-053-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-053-09n	Applicant #:	2001-416XRAB
Received:	February 22, 2001	Effective:	March 24, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO ND SD		
Release destination:	MN ND SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. *with the attached conditions*

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: *Mary J. Hanks*

Signature: (b) (6), (b) (7)(C)

Date: *4-24-01*

State: *MN*

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

APR 23 2001

OR120018_BR_008452



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 26, 2001

Dear Mr. Brown:

Enclosed is notification 01-053-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-053-09n Applicant #: 2001-416XRAB
Received: February 22, 2001 Effective: March 24, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: MN MO ND SD
Release destination: MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 3/7/01

State: MO

Rptloc01/R4



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OR120018_BR_008453

MAR 12 2001



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

W

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 26, 2001

Dear Mr. Nelson:

Enclosed is notification 01-053-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-053-09n Applicant #: 2001-416XRAB
Received: February 22, 2001 Effective: March 24, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: MN MO ND SD
Release destination: MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State Official: David R. Nelson

Signature: (b) (6), (b) (7)(C)

Date: 2-17-01

State: ND

Rptloc01/R4

See attached
letter
confirmations



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APR 18 2001

OR120018_BR_008454



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 26, 2001

Dear Mr. Fridley:

Enclosed is notification 01-053-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-053-09n Applicant #: 2001-416XRAB
Received: February 22, 2001 Effective: March 24, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: MN MO ND SD
Release destination: MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 3/6/01

State: South Dakota

Rptloc01/R4



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MAR 7 2001

OR120018_BR_008455

April 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 24, 2001.

Interstate movement and Release

Notification no. 01-053-09n (2001-416XRAB)

Regulated article - Wheat

Destinations - Minnesota, Missouri, North Dakota, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota has (attached) supplemental conditions.

In addition, the State of North Dakota has (attached) supplemental conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
File number 01-053-09n

OR120018_BR_008456



Minnesota Department of Agriculture (651) 296-1277

April 24, 2001

Ms. Mary Jackson
Biotechnology Program Operations
Permit Unit
USDA APHIS
4700 River Road
Riverdale, MD 27037

Fax: 301-734-8910

RE: Additional Conditions for Release of Wheat 01-053-09n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain entering commercial grain markets must be at least 100 feet.
3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat plants appearing within this area should be destroyed.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial.

Sincerely,

(b) (6), (b) (7)(C)

Mary J. Hanks, Ph.D.
State Biotechnologist

AGRICULTURE COMMISSIONER
ROGER JOHNSON



PHONE (701) 328-2231
(800) 242-7535
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE
State of North Dakota
600 E. Boulevard Ave. Dept. 602
Bismarck, ND 58505-0020

TO: James White
USDA-APHIS-PPQ
Biotechnology Risk Assessment
4700 River Road
Riverdale MD 20737

E. Diane Haimaker
USDA-APHIS-PPQ
Permits-Biotechnology
4700 River Road
Riverdale MD 20737

FROM: David R. Nelson

(b) (6), (b) (7)(C)

DATE: April 17, 2001

RE: Performance Standards for Wheat Notifications

We believe the performance standards for biotechnology wheat trials under notification or permit need to be strengthened to prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial. Standards should be stronger than those used for seed certification purposes because the needs of seed certification differ from the need to prevent persistence in the environment.

Biotechnology wheat trials planned for this and future growing seasons should incorporate the following safeguards:

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed. This distance reflects the pollen movement distances recognized by seed certification standards.
2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat plants appearing within this area should be destroyed.

cc

(b) (6), (b) (7)(C)

Confirmation Report-Memory Send

Time : Apr-24-01 05:09pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 756
Date : Apr-24 05:06pm
To : 916367377085
Document Pages : 03
Start time : Apr-24 05:07pm
End time : Apr-24 05:08pm
Pages sent : 03
Job number : 756

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

April 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 24, 2001.

Interstate movement and Release
Notification no. 01-053-09n (2001-416XRAB)
Regulated article - Wheat
Destinations - Minnesota, Missouri, North Dakota, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota has (attached) supplemental conditions.

In addition, the State of North Dakota has (attached) supplemental conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD



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OR120018_BR_008459

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

May 2, 2001

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

USDA number 01-053-09n, Monsanto id 2001-416XRAB has changed responsible researchers. (b) (6), (b) (7)(C), (b) (4) is now (b) (6), (b) (7)(C), (b) (4) (b) (6), (b) (7)(C), (b) (4) Minnesota (b) (6), (b) (7)(C), (b) (4).

If you have any additional questions, feel free to call (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

cc: S. Wood, USDA, APHIS, PPQ, Raleigh, N. C.
M. Hanks, Minnesota Dept. of Agriculture

OR120018_BR_008460

CONFIDENTIAL

2001 Wheat Field Test Report
USDA #01-053-09n Monsanto #2001-416XRAB

October 16, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147303429	Polk County	MN	
8025	Dakota County	MN	Not Planted
2147308819	Stevens County	MN	
8014	McHenry County	ND	
634	Cass County	ND	
2147308818	Codington County	SD	
2147307538	Brookings County	SD	

Polk County/MN (2147303429)

(b) (4)

(b) (4)

Stevens County/MN (2147308819)

(b) (4)

McHenry County/ND (8014)

(b) (4)

Cass County/ND (634)

(b) (4)

(b) (4)

Codington County/SD (2147308818)

(b) (4)

(b) (4)

Brookings County/SD (2147307538)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

**2001 Wheat Field Test Report
USDA #01-053-09n Monsanto #2001-416XRAB**

October 16, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>	
2147303429	Polk County	MN	
8025	Dakota County	MN	Not Planted
2147308819	Stevens County	MN	
8014	McHenry County	ND	
634	Cass County	ND	
2147308818	Codington County	SD	
2147307538	Brookings County	SD	

Polk County/MN (2147303429)

Planting Date: 05/16/2001

Harvest Date: 08/16/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Stevens County/MN (2147308819)

Planting Date: 05/10/2001

Harvest Date: 08/13/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

McHenry County/ND (8014)

Planting Date: 05/11/2001

Harvest Date: 08/20/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Cass County/ND (634)

Planting Date: 05/14/2001

Harvest Date: 08/17/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Codington County/SD (2147308818)

Planting Date: 05/30/2001

Harvest Date: 09/19/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Brookings County/SD (2147307538)

Planting Date: 05/16/2001

Harvest Date: 08/24/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Planting Date: 05/16/2001

Harvest Date: 08/24/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

3/07/01 2:29 pm

Notification Tracking Sheet

Bp number: 01-059-03n

App number: 2001-429XRAB
Received: 2/28/01
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/30/01
Phenotype: HT - Glyphosate tolerant

Begin movement: 3/29/01
End movement: 3/29/02
Begin release: 3/29/01
End release: 3/29/02
Acre: 2.00
CBI status: CBI

Comments:

Resp person:

Parsed name:

Address1: Monsanto Company

Address2: 700 Chesterfield Parkway N.

Address3:

Address4:

City/State/Zip: Chesterfield, MO 63198

Telephone: (b) (6), (b) (7)(C)

Fax: 636-737-7085

- | | Initial | Date |
|--|---------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [All] | 3/7/01 |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [JT]* | [3/9/01]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex | [KLO] | [3/13/01]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*AZ	*	*WR *
Interstate	*Dest*ND	*	*SCR *
Interstate	*Orig*AZ	*	*WR *
Interstate	*Orig*ND	*	*SCR *
Release	* *ND	*	1*SCR *

[]	[]
[]	[]
[]	[]
[]	[]

- | | | |
|--|---------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [All] | [3/9/01] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [KLO] | [4/19/01]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [KLO] | [4/20/01] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify | | |

Reason for tardiness: (ND) responded on 4/18/2001.

OR120018_BR_008473

MONSANTO

Food • Health • Hope



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-429XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 27, 2001

1. **USDA Reference Number** 01-059-03n

2. **Applicant Reference Number** 2001-429XRAB

3. **Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. **Duration of Introduction**

Interstate Movement and Release

March 29, 2001 - March 29, 2002

5. **Recipient**

Wheat, Triticum aestivum

6. **Regulated Article**

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite and elite lines

Handwritten signature and date: 6/19/01

CONFIDENTIAL

Monsanto Reference ID

2001-429XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2001-429XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 1,000kg. wheat seed to and from each location.

ORIGIN:

AZ, ND

DESTINATION:

AZ, ND

Ship From:

AZ

* [REDACTED] (b) (4) Maricopa County/Province, AZ, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) AZ, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)
]- CBI

ND

* [REDACTED] (b) (4) Walsh County/Province, ND, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA
]- CBI

Ship To:

AZ

* [REDACTED] (b) (4) Maricopa County/Province, AZ, (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID

2001-429XRAB

CONTACT: Mike Wallace, World Wide Wheat, L.L.C., 2850 S. 36th St Suite A-9, Phoenix, AZ, 85034, USA, 602/470-1345

] - CBI

ND

* (b) (4) Walsh County/Province, ND (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-429XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

[(b) (4) Walsh County/Province, ND, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

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PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-429XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 27, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

Monsanto Reference ID

2001-429XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 27, 2001

01-059-03n

1. USDA Reference Number

2. Applicant Reference Number 2001-429XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 29, 2001 - March 29, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite and elite lines

S.I.
4/9/13
see

CBI-DELETED

Monsanto Reference ID

2001-429XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-429XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 1,000kg. wheat seed to and from each location.

ORIGIN:

AZ, ND

DESTINATION:

AZ, ND

Ship From:

AZ

[CBI Deleted] -- *Maricopa County/Province, AZ, USA

ND

[CBI Deleted] -- *Walsh County/Province, ND, USA

Ship To:

AZ

[CBI Deleted] -- *Maricopa County/Province, AZ, USA

CBI-DELETED

Monsanto Reference ID
2001-429XRAB

ND

[CBI Deleted] -- *Walsh County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID

2001-429XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

[CBI Deleted] -- Walsh County/Province, ND, USA, 2 acres

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FAX (636) 737-7085

<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-429XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 27, 2001

NO CBI

2001 Wheat Field Test Report
USDA #01-059-03n Monsanto #2001-429XRAB

October 16, 2002

Biotech Field Compliance Team
Monsanto Company

Location
2147308958

County
Walsh County

State
ND Not Planted

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February 27, 2001

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St. Louis

MO

63198

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Wheat, Triticum aestivum

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HT

Phenotype:

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*J. E. O. - not
all 6/9/13*

CONFIDENTIAL

Monsanto Reference ID

2001-429XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMeVe/l2 --

(b) (4)

CBI

(b) (4)

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Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

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CONFIDENTIAL

Monsanto Reference ID

2001-429XRAB

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Disarmed Agrobacterium tumefaciens

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AZ, ND

DESTINATION:

AZ, ND

Ship From:

AZ

* (b) (4) Maricopa County/Province, AZ, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) AZ,
(b) (4), (b) (6), (b) (7)(C) USA,
]- CBI

ND

* (b) (4) Walsh County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA
]- CBI

Ship To:

AZ

* (b) (4) Maricopa County/Province, AZ, (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID
2001-429XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) AZ,
(b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

ND

*[(b) (4) Walsh County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-429XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

[(b) (4) Walsh County/Province, ND, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER:
(b) (4), (b) (6), (b) (7)(C)
ND, (b) (4), (b) (6), (b) (7)(C) USA

(b) (4), (b) (6), (b) (7)(C)

] - CBI

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Monsanto Company

February 27, 2001

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The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

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IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

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The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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USDA, APHIS, PPQ, BSS

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01-059-03n

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2. Applicant Reference Number 2001-429XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 29, 2001 - March 29, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite and elite lines

Handwritten:
x-IGW-mot
rec 4/9/13

CBI-DELETED

Monsanto Reference ID

2001-429XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-429XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 1,000kg. wheat seed to and from each location.

ORIGIN:

AZ, ND

DESTINATION:

AZ, ND

Ship From:

AZ

[CBI Deleted] -- *Maricopa County/Province, AZ, USA

ND

[CBI Deleted] -- *Walsh County/Province, ND, USA

Ship To:

AZ

[CBI Deleted] -- *Maricopa County/Province, AZ, USA

CBI-DELETED

Monsanto Reference ID
2001-429XRAB

ND

[CBI Deleted] -- *Walsh County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID

2001-429XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (1)

ND

[CBI Deleted] -- Walsh County/Province, ND, USA, 2 acres

MONSANTO

Food • Health • Hope



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-429XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 27, 2001

file copy

Ms. Kathy Cameron, Quarantine Program Manager
Arizona Department of Agriculture
1688 W. Adams St.
Phoenix, AZ 85007

March 7, 2001

Dear Ms. Cameron:

Enclosed is notification 01-059-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-059-03n	Applicant #:	2001-429XRAB
Received:	February 28, 2001	Effective:	March 30, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|
Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008507

S-I.
4/19/01
ul

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

March 7, 2001

Dear Mr. Nelson:

Enclosed is notification 01-059-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-059-03n	Applicant #:	2001-429XRAB
Received:	February 28, 2001	Effective:	March 30, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

JS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

*J-F.D.W. - not
4/19/13
W*

OR120018_BR_008508



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

201-041

Ms. Kathy Cameron, Quarantine Program Manager
Arizona Department of Agriculture
1688 W. Adams St.
Phoenix, AZ 85007

March 7, 2001

Dear Ms. Cameron:

Enclosed is notification 01-059-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-059-03n	Applicant #:	2001-429XRAB
Received:	February 28, 2001	Effective:	March 30, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: G. John Caravetta

Signature: (b) (6), (b) (7)(C)

Date: 3/4/01

State: Arizona

Rpt1oc01/R4



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OR120018_BR_008509



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

W

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

March 7, 2001

Dear Mr. Nelson:

Enclosed is notification 01-059-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-059-03n	Applicant #:	2001-429XRAB
Received:	February 28, 2001	Effective:	March 30, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

David R. Nelson

Signature:

(b) (6), (b) (7)(C)

Date:

4-17-01

State:

ND

Rptloc01/R4

See attached
letter
conditioned

John
4/19/01
JH



APHIS - Protecting American Agriculture

AN EQUIN CREW MEMBER

OR120018_BR_008510

APR 18 2001

5 P. 688 ON

ND AG DEPT

APR. 18. 2001 3:55PM

April 19, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 19, 2001.

Interstate movement and Release
Notification no. 01-059-03n (2001-429XRAB)
Regulated article - Wheat
Destinations - Arizona, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of North Dakota has (attached) supplemental conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

CC:

J. Caravetta, Arizona Dept. of Agric., Phoenix, AZ
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
File number 01-059-03n

L. F. Davis
4/13/01

OR120018_BR_008511

AGRICULTURE COMMISSIONER
ROGER JOHNSON



PHONE (701) 328-2231
(800) 242-7535
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE
State of North Dakota
600 E. Boulevard Ave. Dept. 602
Bismarck, ND 58505-0020

TO: James White E. Diane Hatmaker
USDA-APHIS-PPQ USDA-APHIS-PPQ
Biotechnology Risk Assessment Permits-Biotechnology
4700 River Road 4700 River Road
Riverdale MD 20737 Riverdale MD 20737

FROM: David R. Nelson

(b) (6), (b) (7)(C)

DATE: April 17, 2001

RE: Performance Standards for Wheat Notifications

We believe the performance standards for biotechnology wheat trials under notification or permit need to be strengthened to prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial. Standards should be stronger than those used for seed certification purposes because the needs of seed certification differ from the need to prevent persistence in the environment.

Biotechnology wheat trials planned for this and future growing seasons should incorporate the following safeguards:

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed. This distance reflects the pollen movement distances recognized by seed certification standards.
2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat plants appearing within this area should be destroyed.

cc

(b) (6), (b) (7)(C)

Confirmation Report-Memory Send

Time : Apr-19-01 05:39pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 693
Date : Apr-19 05:35pm
To : 916367377085
Document Pages : 02
Start time : Apr-19 05:38pm
End time : Apr-19 05:39pm
Pages sent : 02

Job number : 693

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

April 19, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 19, 2001.

Interstate movement and Release
Notification no. 01-059-03n (2001-429)RAB)
Regulated article - Wheat
Destinations - Arizona, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of North Dakota has (attached) supplemental conditions. A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:
J. Caravetta, Arizona Dept. of Agric., Phoenix, AZ
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND



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An Equal Opportunity Employer

OR120018_BR_008513

NO CBI

2001 Wheat Field Test Report
USDA #01-059-03n Monsanto #2001-429XRAB

October 16, 2002

Biotech Field Compliance Team
Monsanto Company

Location
2147308958

County
Walsh County

State
ND Not Planted

8-11-03
4/9/13
all

3/07/01 2:29 pm

Notification Tracking Sheet

6/1

*folded
out
4/9/01
HPC*

=====
Bp number: 01-066-03n
=====

App number: 2001-437XRAB
Received: 3/07/01
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 4/06/01
Phenotype: HT - Glyphosate tolerant

Begin movement: 4/04/01
End movement: 4/04/02
Begin release: 4/04/01
End release: 4/04/02
Acre: 2.00
CBI status: CBI

Comments:

Resp person:

Parsed name:

Address1: Monsanto Company

Address2: 700 Chesterfield Parkway N.

Address3:

Address4:

City/State/Zip: Chesterfield, MO 63198

Telephone: (b) (6), (b) (7)(C)

Fax:

636-737-7085

- | | Initial | Date |
|--|-----------------|---------------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>lll</i>] | [<i>5/7/01</i>] |
| 2. <input type="checkbox"/> Review by biotechnologist | [<i>CRR</i>]* | [<i>3-9-01</i>]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KLrd</i>] | [<i>3/13/01</i>]* |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg
Interstate	*Dest*	MN	*	*NER *
Interstate	*Dest*	MO	*	*SCR *
Interstate	*Orig*	MN	*	*NER *
Interstate	*Orig*	MO	*	*SCR *
Release	*	*MN	*	1*NER *

[]	[]
[]	[]
[]	[]
[]	[]

- | | | |
|--|----------------|---------------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>ju</i>] | [<i>3/9/01</i>] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KRD</i>] | [<i>4/23/01</i>]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KRD</i>] | [<i>4/25/01</i>] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify | | |

Reason for tardiness: (MN) Responded on 4/23/2001.

*S-T
4/19/01*

3/7
MONSANTO

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-437XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

March 05, 2001

01-066-03n

1. USDA Reference Number

2. Applicant Reference Number 2001-437XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

April 04, 2001 - April 04, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite and elite lines.

8-4/9/03
I. No. 1
u

CONFIDENTIAL

Monsanto Reference ID

2001-437XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2001-437XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 1500Kg. wheat seed to and from each location.

ORIGIN:

MN, MO

DESTINATION:

MN, MO

Ship From:

MN

*[(b) (4) Ramsey County/Province, MN,
(b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
MN (b) (4), (b) (6), (b) (7)(C) U.S.A.

] - CBI

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A.

] - CBI

Ship To:

MN

*[(b) (4) Ramsey County/Province, MN,
(b) (4) U.S.A.

CONFIDENTIAL

Monsanto Reference ID

2001-437XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C)
MN, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

* (b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C) MO,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-437XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

MN (1)

MN

(b) (4) Ramsey County/Province, MN,
U.S.A., 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-437XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

March 05, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-437XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

March 05, 2001

01-066-03n

1. USDA Reference Number

2. Applicant Reference Number 2001-437XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

April 04, 2001 - April 04, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite and elite lines.

Handwritten note:
6/9/13 - M
I: Not

CBI-DELETED

Monsanto Reference ID

2001-437XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-437XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 1500Kg. wheat seed to and from each location.

ORIGIN:

MN, MO

DESTINATION:

MN, MO

Ship From:

MN

[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

Ship To:

MN

[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.

CBI-DELETED

Monsanto Reference ID
2001-437XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2001-437XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

MN (1)

MN

[CBI Deleted] -- Ramsey County/Province, MN, U.S.A., 2 acres

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CBI-DELETED

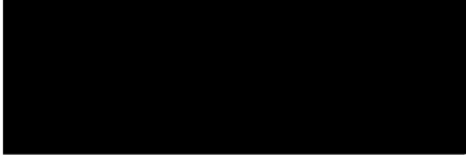
Monsanto Reference ID

2001-437XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

March 05, 2001

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700 CHESTERFIELD PKWY NORTH

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3/7
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700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

April 04, 2001 - April 04, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite and elite lines.

S-I-DW
w/1/13-14

CONFIDENTIAL

Monsanto Reference ID

2001-437XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/2 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/5 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

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CONFIDENTIAL

Monsanto Reference ID

2001-437XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 1500Kg. wheat seed to and from each location.

ORIGIN:

MN, MO

DESTINATION:

MN, MO

Ship From:

MN

* (b) (4) Ramsey County/Province, MN,
(b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
MN (b) (4), (b) (6), (b) (7)(C) U.S.A.

] - CBI

MO

* (b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

Ship To:

MN

* (b) (4) Ramsey County/Province, MN,
(b) (4) U.S.A.

CONFIDENTIAL

Monsanto Reference ID

2001-437XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C)
MN (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

* (b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C) MO,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-437XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (1)

MN

(b) (4) Ramsey County/Province, MN,
U.S.A., 2 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) MN (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

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CONFIDENTIAL

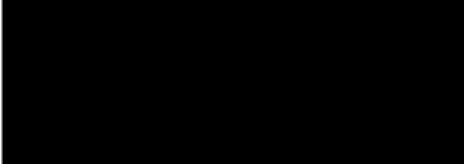
Monsanto Reference ID

2001-437XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

March 05, 2001

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700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

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<http://www.monsanto.com>

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

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Monsanto Reference ID

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March 05, 2001

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63198

4. Duration of Introduction

Interstate Movement and Release

April 04, 2001 - April 04, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite and elite lines.

Handwritten signature and date: 6/19/13

CBI-DELETED

Monsanto Reference ID

2001-437XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

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CBI

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GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

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CBI-DELETED

Monsanto Reference ID

2001-437XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1500Kg. wheat seed to and from each location.

ORIGIN:

MN, MO

DESTINATION:

MN, MO

Ship From:

MN

[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

Ship To:

MN

[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.

CBI-DELETED

Monsanto Reference ID
2001-437XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2001-437XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (1)

MN

[CBI Deleted] -- Ramsey County/Province, MN, U.S.A., 2 acres

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CBI-DELETED

MONSANTO COMPANY

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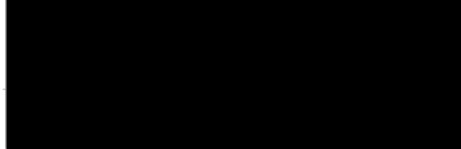
Monsanto Reference ID

2001-437XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

March 05, 2001

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

March 7, 2001

Dear Dr. Hanks:

Enclosed is notification 01-066-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-066-03n	Applicant #:	2001-437XRAB
Received:	March 7, 2001	Effective:	April 6, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

151
Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

*S. J. - 2001
4/9/13
RV*

OR120018_BR_008548

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

March 7, 2001

Dear Mr. Brown:

Enclosed is notification 01-066-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

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Received:	March 7, 2001	Effective:	April 6, 2001
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Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

*S-1/9/13
all
I: nel*

OR120018_BR_008549



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

foxed 4-23-01

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

March 7, 2001

Dear Dr. Hanks:

Enclosed is notification 01-066-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-066-03n

Applicant #: 2001-437XRAB

Received: March 7, 2001

Effective: April 6, 2001

Institution: Monsanto

Recipient: Wheat

Interstate destination: MN-MO

Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. *with the attached conditions*

State DOES NOT CONCUR and offers the following reasons:

Name of State official: *Mary J. Hanks*

Signature: (b) (6), (b) (7)(C)

Date: *4-23-01*

State: *MN*

Rptloc01/R4

*S.I.
4/23/01*



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OR120018_BR_008550

4/23/2001



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

March 7, 2001

Dear Dr. Hanks:

Enclosed is notification 01-066-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-066-03n	Applicant #:	2001-437XRAB
Received:	March 7, 2001	Effective:	April 6, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN-MO		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. *with the attached conditions*
____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

*S. J.
4/9/01*



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APR 23 2001

OR120018_BR_008551



Minnesota Department of Agriculture (651) 296-1277

April 24, 2001

Ms. Mary Jackson
Biotechnology Program Operations
Permit Unit
USDA APHIS
4700 River Road
Riverdale, MD 27037

Fax: 301-734-8910

RE: Additional Conditions for Release of Wheat 01-066-03n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain entering commercial grain markets must be at least 100 feet.
3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat plants appearing within this area should be destroyed.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial.

Sincerely,

(b) (6), (b) (7)(C)

Mary J. Hanks, Ph.D.
State Biotechnologist



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

March 7, 2001

Dear Mr. Brown:

Enclosed is notification 01-066-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-066-03n
Received: March 7, 2001
Institution: Monsanto
Interstate destination: MN-MO
Release destination: MN

Applicant #: 2001-437XRAB
Effective: April 6, 2001
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 3/16/01

State: MO

Rptloc01/R4

*S.I.
4/9/03
WEE*



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OR120018_BR_008555

An Equal Opportunity Employer

MAR 21 2001

April 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 23, 2001.

Interstate movement and Release
Notification no. 01-066-03n (2001-437XRAB)
Regulated article - Wheat
Destinations - Minnesota, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Minnesota has (attached) supplemental conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
File number 01-066-03n

4-26/19/13-162-I-NH

OR120018_BR_008554



Minnesota Department of Agriculture (651) 296-1277

April 24, 2001

Ms. Mary Jackson
Biotechnology Program Operations
Permit Unit
USDA APHIS
4700 River Road
Riverdale, MD 27037

Fax: 301-734-8910

RE: Additional Conditions for Release of Wheat 01-066-03n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain entering commercial grain markets must be at least 100 feet.
3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat plants appearing within this area should be destroyed.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial.

Sincerely,

(b) (6), (b) (7)(C)

Mary J. Hanks, Ph.D.
State Biotechnologist

Confirmation Report-Memory Send

Time : Apr-24-01 05:12pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 758
Date : Apr-24 05:11pm
To : 916367377085
Document Pages : 02
Start time : Apr-24 05:11pm
End time : Apr-24 05:12pm
Pages sent : 02
Job number : 758

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

April 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 23, 2001.

Interstate movement and Release
Notification no. 01-066-03n (2001-437XRAB)
Regulated article - Wheat
Destinations - Minnesota, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Minnesota has (attached) supplemental conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO



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An Equal Opportunity Employer

S-6-973-keel J-Pot

OR120018_BR_008556

CONFIDENTIAL

**2001 Wheat Field Test Report
USDA #01-066-03n Monsanto #2001-437XRAB**

October 2, 2002

**Biotech Field Compliance Team
Monsanto Company**

Location
424036936

County
Ramsey County

State
MN

Ramsey County/MN (424036936)

(b) (4)

*8-6/9/13-LL
L. Damm
mud*

(b) (4)

CBI-DELETED

**2001 Wheat Field Test Report
USDA #01-066-03n Monsanto #2001-437XRAB**

October 2, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
424036936	Ramsey County	MN

Ramsey County/MN (424036936)

Planting Date: 04/28/2001

Harvest Date: 08/07/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

S-4/a/13-ku I:Don

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

8/27/01 9:34 am

Notification Tracking Sheet

Bp number: 01-234-08n

App number: 2001-606XRAB
 Received: 8/22/01
 Institution: Monsanto
 Recipient: Wheat
 Status: Pending
 Effective date: 9/21/01
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: (b) (6), (b) (7)(C)
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway North
 Address3:
 Address4:
 City/State/Zip: St. Louis, MO 63198
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

- | | Initial | Date |
|--|---------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ajd] | [8/28/01] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [RZ]* | AUG 28 2001 |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex | [KZ] | [8/29/01]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*CA	*	*WR *
Interstate	*Dest*KS	*	*SCR *
Interstate	*Dest*MN	*	*NER *
Interstate	*Dest*MO	*	*SCR *
Interstate	*Dest*SD	*	*SCR *
Interstate	*Orig*CA	*	*WR *
Interstate	*Orig*KS	*	*SCR *
Interstate	*Orig*MN	*	*NER *
Interstate	*Orig*MO	*	*SCR *
Interstate	*Orig*SD	*	*SCR *
Release	*CA	*	1*WR *

- | | | |
|--|---------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [ajd] | [8/28/01] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [KZ] | [10/11/01]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [KZ] | [10/12/01] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify | | |

*File scanned
8/19/01*

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2001-606XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

August 22, 2001

01-234-08n

1. USDA Reference Number

2. Applicant Reference Number 2001-606XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)

@Monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 21, 2001 - September 21, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety: Transformed lines derived from Oxen, Ingot, HJ-98

CONFIDENTIAL

Monsanto Reference ID

2001-606XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l12 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l15 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2001-606XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 800,000 lbs of seeds, whole plants, seedlings, immature embryos, pollen, leaves and roots to/from each site

ORIGIN:

CA, KS, MN, MO, SD

DESTINATION:

CA, KS, MN, MO, SD

Ship From:

CA

(b) (4) Imperial County/Province, CA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CA, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

KS

*[(b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

MN

*[(b) (4) Ramsey County/Province, MN, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-606XRAB

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)
U.S.A.,

] - CBI

SD

*[(b) (4) Brookings County/Province, SD,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

Ship To:

CA

*[(b) (4) Imperial County/Province, CA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CA, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

KS

*[(b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-606XRAB

MN

*[REDACTED] (b) (4) Ramsey County/Province, MN,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)
MN, USA, [REDACTED]

] - CBI

MO

*[REDACTED] (b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
U.S.A. (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)

] - CBI

SD

*[REDACTED] (b) (4) Brookings County/Province, SD,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)
SD, USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-606XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CA (1)

CA

[(b) (4) Imperial County/Province, CA, USA, 200 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

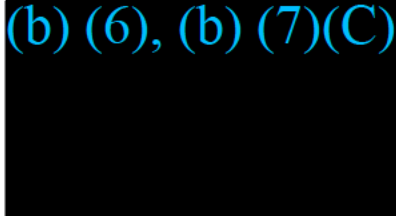
Monsanto Reference ID

2001-606XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 22, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

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Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

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GENE DESCRIPTION

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To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

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CHESTERFIELD, MISSOURI 63198
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FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2001-606XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

August 22, 2001

01-234-08n

1. USDA Reference Number

2. Applicant Reference Number 2001-606XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@Monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 21, 2001 - September 21, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety: Transformed lines derived from Oxen, Ingot, HJ-98

CBI-DELETED

Monsanto Reference ID

2001-606XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

~~CBI-DELETED~~

Monsanto Reference ID

2001-606XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 800,000 lbs of seeds, whole plants, seedlings, immature embryos, pollen, leaves and roots to/from each site

ORIGIN:

CA, KS, MN, MO, SD

DESTINATION:

CA, KS, MN, MO, SD

Ship From:

CA

[CBI Deleted] -- *Imperial County/Province, CA, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MN

[CBI Deleted] -- *Ramsey County/Province, MN, USA

CBI-DELETED

Monsanto Reference ID

2001-606XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

Ship To:

CA

[CBI Deleted] -- *Imperial County/Province, CA, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2001-606XRAB

MN

[CBI Deleted] -- *Ramsey County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

~~CBI-DELETED~~

Monsanto Reference ID

2001-606XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CA (1)

CA

[CBI Deleted] -- Imperial County/Province, CA, USA, 200 acres

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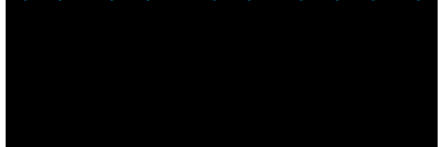
Monsanto Reference ID

2001-606XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 22, 2001

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(b) (4)

(b) (4)

CBI

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(b) (4)

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CONFIDENTIAL

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ORIGIN:

CA, KS, MN, MO, SD

DESTINATION:

CA, KS, MN, MO, SD

Ship From:

CA

*[(b) (4) Imperial County/Province, CA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CA, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

KS

*[(b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) Wichita, KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

MN

*[(b) (4) Ramsey County/Province, MN, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-606XRAB

MO

*[REDACTED] (b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)
U.S.A., [REDACTED]

] - CBI

SD

*[REDACTED] (b) (4) Brookings County/Province, SD,
(b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD (b) (4), (b) (6), (b) (7)(C) SA [REDACTED]

] - CBI

Ship To:

CA

[REDACTED] (b) (4) Imperial County/Province, CA, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) CA (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

KS

*[REDACTED] (b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) KS (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

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MN

*[

(b) (4)

USA

(b) (4)

Ramsey County/Province, MN,

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

MN

USA

(b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[

U.S.A.

(b) (4)

St. Louis County/Province, MO,

(b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

U.S.A.

MO

(b) (4), (b) (6), (b) (7)(C)

] - CBI

SD

*[

(b) (4)

USA

(b) (4)

Brookings County/Province, SD,

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

SD,

USA

(b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-606XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CA (1)

CA

(b) (4)

Imperial County/Province, CA, USA, 200 acres.

RESPONSIBLE PERSON/RESEARCHER:
(b) (4), (b) (6), (b) (7)(C)
CA (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

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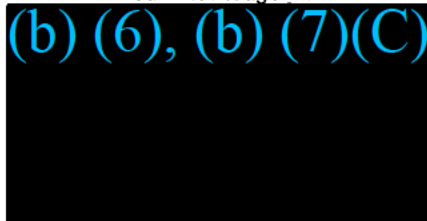
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Monsanto Company

August 22, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

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CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2001-606XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

August 22, 2001

01-234-08n

1. USDA Reference Number

2. Applicant Reference Number 2001-606XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)

@Monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 21, 2001 - September 21, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety: Transformed lines derived from Oxen, Ingot, HJ-98

UN-DELETED

Monsanto Reference ID

2001-606XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate 3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate 3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID

2001-606XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 800,000 lbs of seeds, whole plants, seedlings, immature embryos, pollen, leaves and roots to/from each site

ORIGIN:

CA, KS, MN, MO, SD

DESTINATION:

CA, KS, MN, MO, SD

Ship From:

CA

[CBI Deleted] -- *Imperial County/Province, CA, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MN

[CBI Deleted] -- *Ramsey County/Province, MN, USA

CBI Deleted

Monsanto Reference ID

2001-606XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

Ship To:

CA

[CBI Deleted] -- *Imperial County/Province, CA, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-101.3750

Monsanto Reference ID

2001-606XRAB

MN

[CBI Deleted] -- *Ramsey County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

Monsanto Reference ID

2001-606XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CA (1)

CA

[CBI Deleted] -- Imperial County/Province, CA, USA, 200 acres

MONSANTO



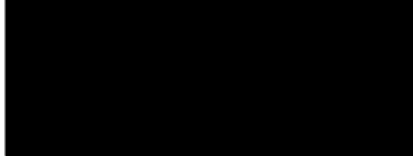
MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID
2001-606XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 22, 2001

file copy

Ms. Barbara Hass, State Regulatory Official
California Department of Food and Agriculture
1220 N Street - Rm A-372
Sacramento, CA 95814

August 27, 2001

Dear Ms. Hass:

Enclosed is notification 01-234-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-234-08n	Applicant #:	2001-606XRAB
Received:	August 22, 2001	Effective:	September 21, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA KS MN MO SD		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181
Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008599

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

August 27, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-234-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-234-08n	Applicant #:	2001-606XRAB
Received:	August 22, 2001	Effective:	September 21, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA KS MN MO SD		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008600

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

August 27, 2001

Dear Dr. Hanks:

Enclosed is notification 01-234-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-234-08n	Applicant #:	2001-606XRAB
Received:	August 22, 2001	Effective:	September 21, 2001
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Interstate destination:	CA KS MN MO SD		
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It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008601

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

August 27, 2001

Dear Mr. Brown:

Enclosed is notification 01-234-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-234-08n	Applicant #:	2001-606XRAB
Received:	August 22, 2001	Effective:	September 21, 2001
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Interstate destination:	CA KS MN MO SD		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008602

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

August 27, 2001

Dear Mr. Fridley:

Enclosed is notification 01-234-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-234-08n	Applicant #:	2001-606XRAB
Received:	August 22, 2001	Effective:	September 21, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA KS MN MO SD		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008603



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Ms. Barbara Hass, State Regulatory Official
California Department of Food and Agriculture
1220 N Street - Rm A-372
Sacramento, CA 95814

August 27, 2001

Dear Ms. Hass:

Enclosed is notification 01-234-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-234-08n Applicant #: 2001-606XRAB
Received: August 22, 2001 Effective: September 21, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: CA KS MN MO SD
Release destination: CA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).
☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature _____

(b) (6), (b) (7)(C)

(916) 654-1017

Date: September 5, 2001

State: California

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_008604

9/5/2001



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

faxed 9-10-01

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

August 27, 2001

Dear Dr. Hanks:

Enclosed is notification 01-234-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Sp number	01-234-08n	Applicant #:	2001-606XRAB
Received:	August 22, 2001	Effective:	September 21, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA KS MN MO SD		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPO, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. *Movement only.*
____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: *Mary J. Hanks*

Signature: (b) (6), (b) (7)(C)

Date: *9-10-01*

State: *MN*

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

August 27, 2001

Dear Mr. Brown:

Enclosed is notification 01-234-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-234-08n Applicant #: 2001-606XRAB
Received: August 22, 2001 Effective: September 21, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: CA KS MN MO SD
Release destination: CA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: _____

(b) (6), (b) (7)(C)

Date: 9/4/01

State: MO

Rptloc01/R4



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SEP 4 2001



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

August 27, 2001

Dear Mr. Fridley:

Enclosed is notification 01-234-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-234-08n	Applicant #:	2001-606XRAB
Received:	August 22, 2001	Effective:	September 21, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA KS MN MO SD		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA



STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 8/30/01

State: South Dakota

Rptloc01/R4



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An Equal Opportunity Employer

SEP 20 2001

OR120018_BR_008607

9/25/01

Called Tom Sim in Kansas, Spoke
to the secretary who suggested
that I call (b) (6), (b) (7)(C)
at (b) (6), (b) (7)(C)

He said Tom Sim will be out
of the office at least another
two weeks, Everything is
on hold he said at this
point.

Re: 01-205-01N

01-229-04N

~~01-229-04N~~

October 11, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after October 11, 2001.

Interstate movement and Release

Notification no. 01-234-08n (2001-606XRAB)

Regulated article - Wheat

Destination - California, Kansas, Minnesota, Missouri, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota concurs with APHIS determination, for movement only.

In addition, the State of California concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:

B. Hass, California Dept. of Food and Agric., Sacramento, CA
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
File number 01-234-08n

OR120018_BR_008609

California Quarantine Requirements
USDA/APHIS Biotechnology Notification No. 01-234-08N

1. Shipments of whole wheat plants, seedlings, and leaves with roots to California from Arizona shall meet the requirements of Section 3277, Title 3, California Code of Regulations, Cereal Leaf Beetle.

Confirmation Report-Memory Send

Time : Oct-12-01 08:43am
Tel line 1 :
Tel line 2 :
Name :

Job number : 702
Date : Oct-12 08:42am
To : 916367377085
Document Pages : 02
Start time : Oct-12 08:42am
End time : Oct-12 08:43am
Pages sent : 02
Job number : 702

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

October 11, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after October 11, 2001.

Interstate movement and Release
Notification no. 01-234-08n (2001-606KRAB)
Regulated article - Wheat
Destination - California, Kansas, Minnesota, Missouri, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota concurs with APHIS determination, for movement only.

In addition, the State of California concurs with APHIS determination, provided, all applicable quarantine requirements are met (see attached).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:

B. Hass, California Dept. of Food and Agric., Sacramento, CA
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
K. Fridley, South Dakota Dept. of Agric., Pierre, SD



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An Equal Opportunity Employer

OR120018_BR_008611

NOTIFICATION FIELD SITE INSPECTION WORKSHEET

When completed this is a PPQ Internal Document

APHIS NOTIFICATION NUMBER(s): 01-234-08n

CROP: Wheat

APPLICANTS NAME (b) (6), (b) (7)(C)

TRAIT/GENE: Glyphosate Tolerant

NAME OF COOPERATOR AT INSPECTED SITE (b) (6), (b) (7)(C)

PHONE: (b) (6), (b) (7)(C)

LOCATION OF SITE Imperial county DATE OF INSPECTION November 9, 2001

TYPE OF LOCATION: FARM ☒ NURSERY ☐ RESEARCH ☐ OTHER ☐ (DESCRIBE) _____

GPS COORDINATES (If available): LATITUDE N/A LONGITUDE _____

PROVIDE ANSWERS BELOW. CIRCLE "Y" FOR YES AND "N" FOR NO. IF THE ANSWER TO ANY QUESTION IS "NO" OR COULD NOT BE ANSWERED AT THE TIME OF THE INSPECTION, EXPLAIN THESE IN A COVER LETTER SUBMITTED WITH THIS REPORT TO THE REGIONAL PROGRAM MANAGER.

I. Shipping, Maintenance at Destination, and Identification

A. Did all aspects of field trial maintain identify (seed storage, planting-harvest site, field cages, etc.)? Y N

Yes

B. Was a site map obtained or drawn by you for reference later? (For harvest, flower removal, volunteers, etc.)? Y N

Yes

II. Field test Site Requirements addressing Inadvertent Mixing, Persistence and Volunteer Plants

A. If there were any other cultivated plantings of the crop within the vicinity of the field test, were they located outside the pollination distance for the crop? Y N

Yes

B. If the transgenic plant is sexually compatible with free-living plants, were there no compatible species located outside the pollination distance for the plants? Y N

Yes

C. Which of the 5 containment options is the applicant using? Check one below. If none, please note it here and state this in your cover letter to the Regional Program Manager. c-4

____ 1. Removing flowers.

C.1. Is there any evidence that the plants have flowers or that flowers have been removed? Y N

____ 2. Bagging flowers/tassels

C.2. Does the applicant have material to bag reproductive structures? Y N

____ 3. Terminating the experiment before flowering.

C. 3. Were plants destroyed or removed from the field before any flowers were allowed to release pollen? Y N

☒ 4. Physical isolation.

*Qh 11/16/01
iVAR*

OR120018_BR_008612

MSD

C. 4. If there are any non-transgenic compatible plants within the distance stated in Table 1, were the non-transgenic plants within the pollination distances being treated as transgenic and disposed of and monitored for volunteers by the same methods used for the transgenics?

_____ 5. Temporal isolation.

C.5. Is there evidence that the flowering times of the transgenic plant and any non-transgenic plants will not overlap and is the applicant monitoring the plants to ensure that flowering times do not overlap? Y N

D. If the applicant's design standards use border rows, are there the state number of border rows? Y N
Yes

E. Is there an alley or other marking system to separate any transgenic from non-transgenic plants of the same species? Y N

Yes

F. If transgenic plants were grown the previous year, were volunteers removed according to the design standards? Y N

Yes

G. Does the applicant anticipate volunteers and have the necessary chemical or equipment as stated in their design standards? Y N

Yes

H. Was the field site marked as stated in their design standards? Y N

Yes

I. Does the applicant have an area designated to clean the machinery that may contain seeds or reproductive Parts? Y N

Yes

J. If seeds or reproductive parts are washed off the equipment, does the applicant have a way to ensure that they do not survive? Y N

Yes

III. Devitalization.

A. Does the applicant have the necessary equipment to devitalize the plant material as described in their design standards (e.g., an autoclave, steamer, burial pit, incineration)? Y N

Yes

B. Remind applicants that their transgenic plants can not be used for food or feed unless consultation with the Food and Drug Administration (FDA) regarding the transgenic plants has been successfully completed.

INSPECTING OFFICER Nicolas Coronel PHONE (760) 768-2540

LOCATION OF PPQ OFFICE Calexico, Ca.

NAMES & AFFILIATIONS OF ANY OTHER PERSONS AT THE INSPECTION _____

Mario Tellez, PPQO

RETURN COMPLETED WORKSHEET TO Regional Program Manager for Biotechnology in your Region

CONFIDENTIAL

2001 Wheat Field Test Report
USDA #01-234-08n **Monsanto #2001-606XRAB**

March 21, 2003

Biotech Field Compliance Team
Monsanto Company

Location
887199712

County
Imperial

State
CA

Imperial County/CA (887199712)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2001 Wheat Field Test Report
USDA #01-234-08n Monsanto #2001-606XRAB

March 21, 2003

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
887199712	Imperial	CA

Imperial County/CA (887199712)

Planting Date: 11/08/2001

Destruct Date: 02/02/2002

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

8/27/01 9:34 am

Notification Tracking Sheet

Bp number: 01-236-02n

App number: 2001-613XRAB
 Received: 8/24/01
 Institution: Monsanto
 Recipient: Wheat
 Status: Pending
 Effective date: 9/23/01
 Phenotype: HT - Glyphosate tolerant
 Comments:

Begin movement: 9/22/01
 End movement: 9/22/02
 Begin release: 9/22/01
 End release: 9/22/02
 Acre: 5.00
 CBI status: CBI

Resp person: (b) (6), (b) (7)(C)
 Parsed name:

Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway North
 Address3:
 Address4:
 City/State/Zip: St. Louis, MO 63198
 Telephone: (b) (6), (b) (7)(C)

Fax: 636-737-7085

- | | Initial | Date |
|--|-----------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [CJD] | [8/28/01] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [RZP] * | AUG 28 2001 |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex | [KLN] | [8/29/01] * |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*HI	*	*WR *
Interstate	*Dest*MO	*	*SCR *
Interstate	*Orig*HI	*	*WR *
Interstate	*Orig*MO	*	*SCR *
Release	* *HI	*	1*WR *

- | | | |
|--|---------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [CJD] | [8/29/01] |
| 6. <input checked="" type="checkbox"/> Letter of (acknowledgement) denial/withdraw | [KLN] | [10/1/01] * |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [KLN] | [10/5/01] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify | | |

OR120018_BR_008618

MONSANTO



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700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
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FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2001-613XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

August 23, 2001

01-236-02n

1. USDA Reference Number

2. Applicant Reference Number 2001-613XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@Monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 22, 2001 - September 22, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

glyphosate-tolerant

Cultivar/Variety: transformed lines derived from Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2001-613XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2001-613XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 10,000 lbs of wheat seed, whole plants, seedlings, immature embryos, pollen, leaves, and roots.

ORIGIN:

HI, MO

DESTINATION:

HI, MO

Ship From:

HI

*[(b) (4) Honolulu County/Province,
HI, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Honolulu
County/Province, HI, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
U.S.A., (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-613XRAB

Ship To:

HI

*[(b) (4)] Honolulu County/Province,
HI, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4)] Honolulu
County/Province, HI, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b) (4)] St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO (b) (4), (b) (6), (b) (7)(C)
U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-613XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

HI (1)

HI

(b) (4) Honolulu County/Province,
HI, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO



CONFIDENTIAL

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FAX (636) 737-7085
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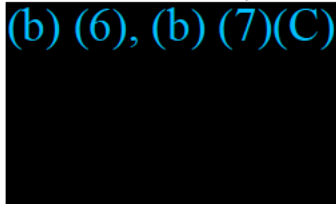
Monsanto Reference ID

2001-613XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 23, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

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Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2001-613XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

August 23, 2001

01-236-02n

1. USDA Reference Number

2. Applicant Reference Number 2001-613XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)

2Monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 22, 2001 - September 22, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

glyphosate-tolerant

Cultivar/Variety: transformed lines derived from Bobwhite

~~CBI-DELETED~~

Monsanto Reference ID

2001-613XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-613XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 10,000 lbs of wheat seed, whole plants, seedlings, immature embryos, pollen, leaves, and roots.

ORIGIN:

HI, MO

DESTINATION:

HI, MO

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, USA

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID
2001-613XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, USA

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2001-613XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

[CBI Deleted] -- Honolulu County/Province, HI, USA, 5 acres

MONSANTO



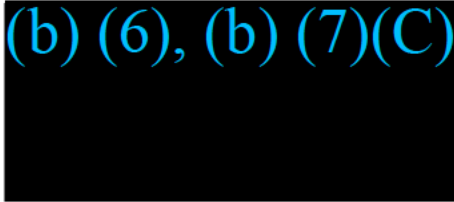
MONSANTO COMPANY
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Monsanto Reference ID
2001-613XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company
August 23, 2001

MONSANTO



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August 23, 2001

01-236-02n

1. USDA Reference Number

2. Applicant Reference Number 2001-613XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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EMail

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700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 22, 2001 - September 22, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

glyphosate-tolerant

Cultivar/Variety: transformed lines derived from Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2001-613XRAB

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GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2001-613XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 10,000 lbs of wheat seed, whole plants, seedlings, immature embryos, pollen, leaves, and roots.

ORIGIN:

HI, MO

DESTINATION:

HI, MO

Ship From:

HI

*[(b) (4) Honolulu County/Province,
HI, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Honolulu
County/Province, HI, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
U.S.A. (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-613XRAB

Ship To:

HI

* [REDACTED] (b) (4) Honolulu County/Province,
HI, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

* [REDACTED] (b) (4) Honolulu
County/Province, HI (b) (4) U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

* [REDACTED] (b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)
U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-613XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

(b) (4) Honolulu County/Province,
HI, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

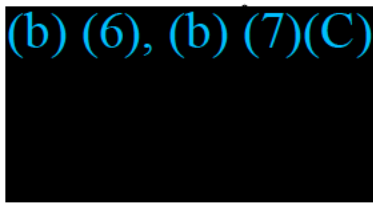
Monsanto Reference ID

2001-613XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 23, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

MONSANTO



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID
2001-613XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

August 23, 2001

01-236-02n

1. USDA Reference Number
2. Applicant Reference Number 2001-613XRAB
3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis MO

63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@Monsanto.com

4. Duration of Introduction

Interstate Movement and Release

September 22, 2001 - September 22, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

glyphosate-tolerant

Cultivar/Variety: transformed lines derived from Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2001-613XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMOVa/I2 -- [CBI Deleted]

CBI

Gene: ~~CTP2-CP4~~ A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: ~~CTP2-CP4~~ A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-613XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 10,000 lbs of wheat seed, whole plants, seedlings, immature embryos, pollen, leaves, and roots.

ORIGIN:

HI, MO

DESTINATION:

HI, MO

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, USA

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

~~CBI DELETED~~

Monsanto Reference ID

2001-613XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, USA

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

OR120018_BR_008649

Monsanto Reference ID

2001-613XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

[CBI Deleted] -- Honolulu County/Province, HI, USA, 5 acres

MONSANTO



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

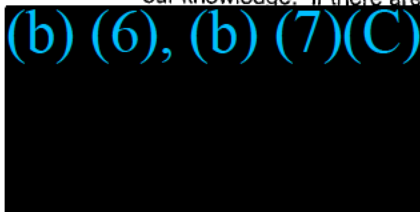
Monsanto Reference ID

2001-613XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 23, 2001

file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

August 27, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-236-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-236-02n	Applicant #:	2001-613XRAB
Received:	August 24, 2001	Effective:	September 23, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MO		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008651

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

August 27, 2001

Dear Mr. Brown:

Enclosed is notification 01-236-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-236-02n	Applicant #:	2001-613XRAB
Received:	August 24, 2001	Effective:	September 23, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MO		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008652

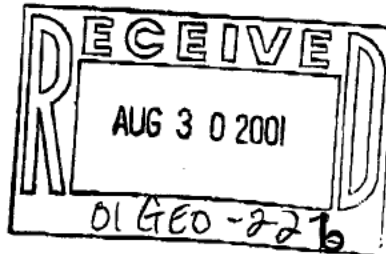


United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813



August 27, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-236-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-236-02n	Applicant #:	2001-613XRAB
Received:	August 24, 2001	Effective:	September 23, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MO		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

Post-it* Fax Note	7671	Date	# of pages
To	M. Jackson	From	C. Okada
Co./Dept.		Co.	
Phone #		Phone #	
Fax #		Fax #	

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo ST., Honolulu, HI 96813.
☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

Signature: (b) (6), (b) (7)(C)

Date: 28 September 2001

State: Hawaii

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OCT 1 2001

OR120018_BR_008653



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

August 27, 2001

Dear Mr. Brown:

Enclosed is notification 01-236-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-236-02n	Applicant #:	2001-613XRAB
Received:	August 24, 2001	Effective:	September 23, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MO		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 9/4/01

State: MO

Rptloc01/R4



APHIS - Protecting American Agriculture

OR120018-BK-008654 An Equal Opportunity Employer

SEP 4 2001

P.01/10 2737510005

DEPT OF AGRICULTURE

SEP-06-2001 14:18

October 1, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after October 1, 2001.

Interstate movement and Release
Notification no. 01-236-02n (2001-613XRAB)
Regulated article - Wheat
Destinations - Hawaii, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
 - a) The germination of volunteer wheat after harvest.
 - b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.

The report should be submitted to the Plant Quarantine Branch, 701 Ilalo Street, Honolulu, Hawaii, 96813, with a copy to Ms. Carol Okada, within six months of completion or termination of the test.

OR120018_BR_008655

4. The introduction of any organism other than corn seeds may be regulated by the Plant Quarantine Branch. For more information on the organisms regulated by the Branch, please contact Mr. Myron Isherwood Jr., Hawaii Department of Agriculture.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:
M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
File number 01-236-02n

Confirmation Report-Memory Send

Time : Oct-05-01 09:00am
Tel line 1 :
Tel line 2 :
Name :

Job number : 608
Date : Oct-05 08:59am
To : 916367377085
Document Pages : 02
Start time : Oct-05 08:59am
End time : Oct-05 09:00am
Pages sent : 02
Job number : 608

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

October 1, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after October 1, 2001.

Interstate Movement and Release
Notification no. 01-236-02a (2001-613XRAB)
Regulated article - Wheat
Destinations - Hawaii, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
 - a) The germination of volunteer wheat after harvest.
 - b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.

The report should be submitted to the Plant Quarantine Branch, 701 Ilalo Street, Honolulu, Hawaii, 96813, with a copy to Ms. Carol Okada, within six months of completion or termination of the test.



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_008657

MONSANTO



No CBI

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

March 27, 2003

Mr. Tony Roman
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Mr. Roman;

Re: Field Test Report.

Field releases under the following USDA notifications have been completed and we are now submitting final reports as required. Please find reports for

USDA #

01-236-021

Monsanto #

2001-613XRAB

If you have any questions, please call (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

OR120018_BR_008658

CONFIDENTIAL

2001 Wheat Field Test Report
USDA #01-236-02n **Monsanto #2001-613XRAB**

March 27, 2003

Biotech Field Compliance Team
Monsanto Company

Location
2147305396

County
Honolulu

State
HI

Honolulu County/HI (2147305396)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

MONSANTO



No CBI

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

March 27, 2003

Mr. Tony Roman
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Mr. Roman;

Re: Field Test Report.

Field releases under the following USDA notifications have been completed and we are now submitting final reports as required. Please find reports for

USDA #

201-236-021

Monsanto #

2001-613XRAB

If you have any questions, please call (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

OR120018_BR_008663

CBI-DELETED

2001 Wheat Field Test Report
USDA #01-236-02n Monsanto #2001-613XRAB

March 27, 2003

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147305396	Honolulu	HI

Honolulu County/HI (2147305396)

Planting Date: 10/19/2001

Destruct Date: 04/12/2002

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

8/27/01 9:34 am

Notification Tracking Sheet

=====

Bp number: 01-236-04n

=====

App number: 2001-615XRAB

Received: 8/24/01

Institution: Monsanto

Recipient: Wheat

Status: Pending

Effective date: 9/23/01

Phenotype: HT - Glyphosate tolerant

Comments:

Resp person:

Parsed name:

Address1: Monsanto Company

Address2: 700 Chesterfield Parkway North

Address3:

Address4:

City/State/Zip: St. Louis, MO 63198

Telephone: (b) (6), (b) (7)(C)

Begin movement: 9/22/01

End movement: 9/22/02

Begin release: 9/22/01

End release: 9/22/02

Acre: 4.00

CBI status: CBI

- =====
- | | Initial | Date |
|--|---------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ajb] | [8/28/01] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [KZ]* | AUG 28 2001 |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex | [KZ] | [8/29/01]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg			
Interstate	*Dest	*AZ	*	*WR	*	[] []
Interstate	*Dest	*CA	*	*WR	*	[] []
Interstate	*Dest	*MO	*	*SCR	*	[] []
Interstate	*Dest	*MT	*	*WR	*	[] []
Interstate	*Orig	*AZ	*	*WR	*	
Interstate	*Orig	*CA	*	*WR	*	
Interstate	*Orig	*MO	*	*SCR	*	
Interstate	*Orig	*MT	*	*WR	*	
Release	*	*CA	*	1*WR	*	[] []

5. ☒ Enter genes into database [ajb] [8/28/01]
6. ☒ Letter of acknowledgement/denial/withdraw [KZ] [9/21/01]*
7. ☒ Enter final data into database [KZ] [9/26/01]
8. ☐ If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify

File removed for
I: sum, Not
8/19/01
all

MONSANTO



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CHESTERFIELD, MISSOURI 63198
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<http://www.monsanto.com>

Monsanto Reference ID
2001-615XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

August 23, 2001

01-236-04n

1. USDA Reference Number

2. Applicant Reference Number 2001-615XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@Monsanto.com

Monsanto Company
700 Chesterfield Parkway North
St. Louis MO 63198

4. Duration of Introduction

Interstate Movement and Release

September 22, 2001 - September 22, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

glyphosate-tolerant

Cultivar/Variety: transformed lines derived from Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2001-615XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4) (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b) (4) (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2001-615XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 5000 lbs of wheat seed, whole plants, seedlings, immature embryos, pollen, leaves, and roots

ORIGIN:
AZ, CA, MO, MT

DESTINATION:
AZ, CA, MO, MT

Ship From:

AZ

* (b) (4) Yuma County/Province, AZ, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) AZ (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

CA

* (b) (4) Imperial County/Province, CA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CA, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

MO

* (b) (4) St. Louis County/Province, MO, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) U.S.A.

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-615XRAB

MT

*[(b) (4)] Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

Ship To:

AZ

*[(b) (4)] Yuma County/Province, AZ, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) AZ, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

CA

*[(b) (4)] Imperial County/Province, CA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CA, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

MO

*[(b) (4)] St. Louis County/Province, MO, (b) (4) U.S.A.

CONFIDENTIAL

Monsanto Reference ID

2001-615XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)
U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

MT

*[(b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-615XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CA (1)

CA

(b) (4)

Imperial County/Province, CA, USA, 4 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

AZ,

(b) (4), (b) (6), (b) (7)(C)

USA,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO



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FAX (636) 737-7085
<http://www.monsanto.com>

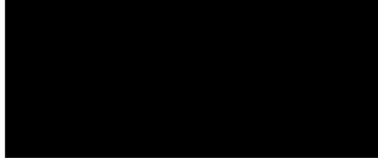
Monsanto Reference ID

2001-615XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 23, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

MONSANTO



CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2001-615XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

August 23, 2001

01-236-04n

1. USDA Reference Number

2. Applicant Reference Number 2001-615XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@Monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 22, 2001 - September 22, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

glyphosate-tolerant

Cultivar/Variety: transformed lines derived from Bobwhite

CBI-DELETED

Monsanto Reference ID

2001-615XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-615XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 5000 lbs of wheat seed, whole plants, seedlings, immature embryos, pollen, leaves, and roots

ORIGIN:

AZ, CA, MO, MT

DESTINATION:

AZ, CA, MO, MT

Ship From:

AZ

[CBI Deleted] -- *Yuma County/Province, AZ, USA

CA

[CBI Deleted] -- *Imperial County/Province, CA, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2001-615XRAB

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

Ship To:

AZ

[CBI Deleted] -- *Yuma County/Province, AZ, USA

CA

[CBI Deleted] -- *Imperial County/Province, CA, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID
2001-615XRAB

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2001-615XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CA (1)

CA

[CBI Deleted] -- Imperial County/Province, CA, USA, 4 acres

MONSANTO



CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

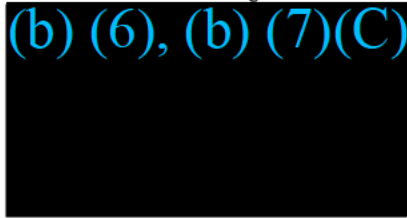
Monsanto Reference ID

2001-615XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 23, 2001

MONSANTO



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2001-615XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

August 23, 2001

01-236-04n

1. USDA Reference Number

2. Applicant Reference Number 2001-615XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@Monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 22, 2001 - September 22, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

glyphosate-tolerant

Cultivar/Variety: transformed lines derived from Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2001-615XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2001-615XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 5000 lbs of wheat seed, whole plants, seedlings, immature embryos, pollen, leaves, and roots

ORIGIN:

AZ, CA, MO, MT

DESTINATION:

AZ, CA, MO, MT

Ship From:

AZ

* [REDACTED] (b) (4) Yuma County/Province, AZ, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) AZ, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

CA

* [REDACTED] (b) (4) Imperial County/Province, CA, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) CA, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

MO

* [REDACTED] (b) (4) St. Louis County/Province, MO, (b) (4) U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-615XRAB

MT

*[(b) (4)] Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

Ship To:

AZ

*[(b) (4)] Yuma County/Province, AZ, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) AZ, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

CA

*[(b) (4)] Imperial County/Province, CA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CA, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

MO

*[(b) (4)] St. Louis County/Province, MO, (b) (4) U.S.A.

CONFIDENTIAL

Monsanto Reference ID

2001-615XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)
U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MT

*[(b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

~~CONFIDENTIAL~~

Monsanto Reference ID

2001-615XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CA (1)

CA

(b) (4)

Imperial County/Province, CA, USA, 4 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) AZ (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

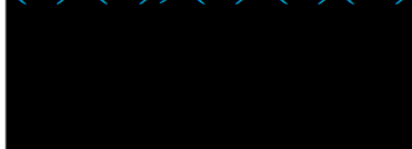
Monsanto Reference ID

2001-615XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 23, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

MONSANTO



CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2001-615XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

August 23, 2001

01-236-04n

1. USDA Reference Number

2. Applicant Reference Number 2001-615XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@Monsanto.com

4. Duration of Introduction

Interstate Movement and Release

September 22, 2001 - September 22, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

glyphosate-tolerant

Cultivar/Variety: transformed lines derived from Bobwhite

CBI-DELETED

Monsanto Reference ID

2001-615XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: ~~CTP2-CP4~~ A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal ~~5-enolpyruvylshikimate-3-phosphate synthase gene (CP4)~~ from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: ~~CTP2-CP4~~ A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal ~~5-enolpyruvylshikimate-3-phosphate synthase gene (CP4)~~ from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-615XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 5000 lbs of wheat seed, whole plants, seedlings, immature embryos, pollen, leaves, and roots

ORIGIN:

AZ, CA, MO, MT

DESTINATION:

AZ, CA, MO, MT

Ship From:

AZ

[CBI Deleted] -- *Yuma County/Province, AZ, USA

CA

[CBI Deleted] -- *Imperial County/Province, CA, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2001-615XRAB

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

Ship To:

AZ

[CBI Deleted] -- *Yuma County/Province, AZ, USA

CA

[CBI Deleted] -- *Imperial County/Province, CA, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

~~CBI-DELETED~~

Monsanto Reference ID

2001-615XRAB

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

~~CBI-DELETED~~

Monsanto Reference ID

2001-615XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CA (1)

CA

[.CBI Deleted] -- Imperial County/Province, CA, USA, 4 acres

MONSANTO



CB1-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-615XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

August 23, 2001

file copy

Mr. John Caravetta, Associate Director
Arizona Department of Agriculture
1688 W. Adams St.
Phoenix, AZ 85007

August 27, 2001

Dear Mr. Caravetta:

Enclosed is notification 01-236-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-236-04n	Applicant #:	2001-615XRAB
Received:	August 24, 2001	Effective:	September 23, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ CA MO MT		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

JS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008702

file copy

Ms. Barbara Hass, State Regulatory Official
California Department of Food and Agriculture
1220 N Street - Rm A-372
Sacramento, CA 95814

August 27, 2001

Dear Ms. Hass:

Enclosed is notification 01-236-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-236-04n	Applicant #:	2001-615XRAB
Received:	August 24, 2001	Effective:	September 23, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ CA MO MT		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008703

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

August 27, 2001

Dear Mr. Brown:

Enclosed is notification 01-236-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-236-04n	Applicant #:	2001-615XRAB
Received:	August 24, 2001	Effective:	September 23, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ CA MO MT		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

JS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008704

file copy

Ms. Mary Bryson, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

August 27, 2001

Dear Ms. Bryson:

Enclosed is notification 01-236-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-236-04n	Applicant #:	2001-615XRAB
Received:	August 24, 2001	Effective:	September 23, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ CA MO MT		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008705



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. John Caravetta, Associate Director
Arizona Department of Agriculture
1688 W. Adams St.
Phoenix, AZ 85007

August 27, 2001

Dear Mr. Caravetta:

Enclosed is notification 01-236-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-236-04n	Applicant #:	2001-615XRAB
Received:	August 24, 2001	Effective:	September 23, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ CA MO MT		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: G. John Caravetta

Signature: (b) (6), (b) (7)(C)

Date: 9/19/01

State: AZ

Rptloc01/R4



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An Equal Opportunity Employer

SEP 20 2001

OR120018_BR_008706

TOTAL P.02



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Ms. Barbara Hass, State Regulatory Official
California Department of Food and Agriculture
1220 N Street - Rm A-372
Sacramento, CA 95814

August 27, 2001

Dear Ms. Hass:

Enclosed is notification 01-236-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-236-04n Applicant #: 2001-615XRAB
Received: August 24, 2001 Effective: September 23, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: AZ CA MO MT
Release destination: CA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).
☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Barbara I. Hass (916) 654-1017

Signature (b) (6), (b) (7)(C)

Date: September 5, 2001

State: California

Rptloc01/R4



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OR120018_BR_008707

SEP 5 2001



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

August 27, 2001

Dear Mr. Brown:

Enclosed is notification 01-236-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-236-04n	Applicant #:	2001-615XRAB
Received:	August 24, 2001	Effective:	September 23, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ CA MO MT		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E Brown

Signature: (b) (6), (b) (7)(C)

Date: 9/4/01

State: MO

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_008708

07/50 P.05/10 50001510005

DEPT OF AGRICULTURE

SEP-06-2001 14:19

SEP 4 2001



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

~~Ms. Mary Bryson, Administrator~~
~~Agriculture Sciences Division~~
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

*Please change
to: Gregory H. Ames, Administrator*

August 27, 2001

Dear Ms. Bryson:

Enclosed is notification 01-236-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-236-04n	Applicant #:	2001-615XRAB
Received:	August 24, 2001	Effective:	September 23, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ CA MO MT		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: **(b) (6), (b) (7)(C)**

Date: 8/31/01

State: Montana

Rptloc01/R4

P



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AUG 31 2001

OR120018_BR_008709

September 21, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after September 23, 2001.

Interstate movement and Release
Notification no. 01-236-04n (2001-615XRAB)
Regulated article - Wheat
Destinations - Arizona, California, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:

J. Caravetta, Arizona Dept. of Agric., Phoenix, AZ
B. Hass, California Dept. of Food and Agric., Sacramento, CA
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Ames, Montana Dept. of Agric., Helena, MT
File number 01-236-04n

OR120018_BR_008710

California Quarantine Requirements
USDA/APHIS Biotechnology Notification No. 01-236-04N

1. Shipments of wheat plants with roots to California from Arizona shall meet the Requirements of Section 3261, Title 3, California Code of Regulations, Ozonium Root Rot.
2. Shipments of all whole wheat plants, seedlings, and leaves to California from all states and districts of the United States east of and including Missouri shall meet the requirements of Section 3277, Title 3, California Code of Regulations, Cereal Leaf Beetle.

Confirmation Report-Memory Send

Time : Sep-24-01 05:02pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 505
Date : Sep-24 05:01pm
To : 916367377085
Document Pages : 02
Start time : Sep-24 05:01pm
End time : Sep-24 05:02pm
Pages sent : 02
Job number : 505

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

September 21, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after September 23, 2001.

Interstate movement and Release
Notification no. 01-236-04n (2001-615XRAB)
Regulated article - Wheat
Destinations - Arizona, California, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:
J. Caravetta, Arizona Dept. of Agric., Phoenix, AZ
B. Hass, California Dept. of Food and Agric., Sacramento, CA
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Ames, Montana Dept. of Agric., Helena, MT



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OR120018_BR_008712

CONFIDENTIAL

2001 Wheat Field Test Report
USDA #01-236-04n **Monsanto #2001-615XRAB**

March 21, 2003

Biotech Field Compliance Team
Monsanto Company

Location
887199712

County
Imperial

State
CA

Imperial County/CA (887199712)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2001 Wheat Field Test Report
USDA #01-236-04n Monsanto #2001-615XRAB

March 21, 2003

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
887199712	Imperial	CA

Imperial County/CA (887199712)

Planting Date: 11/07/2001

Harvest Date: 05/01/2002

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

12/17/01 11:55 am

Notification Tracking Sheet

=====

Bp number: 01-348-13n

=====

App number: 2001-807XRAB Begin movement: 1/12/02
 Received: 12/14/01 End movement: 1/12/03
 Institution: Monsanto Begin release: 1/12/02
 Recipient: Wheat End release: 1/12/03
 Status: Pending Acre: 8.00
 Effective date: 1/13/02 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: **(b) (6), (b) (7)(C)**
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: **(b) (6), (b) (7)(C)** Fax: 636-737-7085

- | | Initial | Date |
|--|--------------------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>gid</i>] | [12/18/01] |
| 2. <input type="checkbox"/> Review by biotechnologist | [<i>sn</i>]* | []* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>K&L</i>] | [12/21/01]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*KS	*	*SCR *
Interstate	*Dest*MO	*	*SCR *
Interstate	*Dest*MT	*	*WR *
Interstate	*Dest*OR	*	*WR *
Interstate	*Dest*WA	*	*WR *
Interstate	*Orig*KS	*	*SCR *
Interstate	*Orig*MO	*	*SCR *
Interstate	*Orig*MT	*	*WR *
Interstate	*Orig*OR	*	*WR *
Interstate	*Orig*WA	*	*WR *
Release	* *OR	*	2*WR *

- | | | |
|--|--------------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>apd</i>] | [12/19/01] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>K&L</i>] | [1/8/02]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>K&L</i>] | [1/9/02] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify | | |

OR120018_BR_008718

7

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2001-807XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-348-13n

1. USDA Reference Number

2. Applicant Reference Number 2001-807XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

January 12, 2002 - January 12, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Variety: Bobwhite

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Monsanto Reference ID

2001-807XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID

2001-807XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

1000 Ship up to 300 pounds wheat seed to and from each location.

ORIGIN:

KS, MO, MT, OR, WA

DESTINATION:

KS, MO, MT, OR, WA

Ship From:

KS

*[(b) (4) Sedgwick County/Province, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) U.S.A.

] - CBI

MT

*[(b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-807XRAB

OR

*[(b) (4), (b) (6), (b) (7)(C) Umatilla County/Province, OR (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Umatilla County/Province, OR, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) OR, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

WA

*[(b) (4) Benton County/Province, WA (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4), (b) (6), (b) (7)(C) Grant County/Province, WA (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-807XRAB

Ship To:

KS

*[(b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MT

*[(b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

OR

*[(b) (4), (b) (6), (b) (7)(C) Umatilla County/Province, OR, (b) (4), (b) (6), (b) (7)(C) USA

CONFIDENTIAL

Monsanto Reference ID
2001-807XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

*(b) (4)
Umatilla County/Province, OR, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) OR, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

WA
*(b) (4) Benton County/Province, WA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

*(b) (4), (b) (6), (b) (7)(C) Grant County/Province, WA, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-807XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

OR (2)

OR

(b) (4), (b) (6), (b) (7)(C) Umatilla County/Province, OR, USA, 5 acres.
(b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4)
Umatilla County/Province, OR, USA, 3 acres. (2147306779)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) OR, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

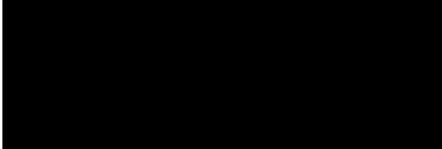
Monsanto Reference ID

2001-807XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description (referred to as vector components) category includes the names and information about genes and their expressed traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically,

Monsanto ID: 2001-807XRAB

information concerning marketing strategies, and the names of independent contractors participating in a

company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto.

Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2001-807XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-348-13n

1. USDA Reference Number

2. Applicant Reference Number 2001-807XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

January 12, 2002 - January 12, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Variety: Bobwhite

CBI-DELETED

Monsanto Reference ID

2001-807XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-807XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

1000 Ship up to 300 pounds wheat seed to and from each location.

ORIGIN:

KS, MO, MT, OR, WA

DESTINATION:

KS, MO, MT, OR, WA

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2001-807XRAB

OR

[CBI Deleted] -- *Umatilla County/Province, OR, USA

[CBI Deleted] -- *Umatilla County/Province, OR, USA

WA

[CBI Deleted] -- *Benton County/Province, WA, USA

[CBI Deleted] -- *Grant County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID
2001-807XRAB

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

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MT

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Monsanto Reference ID
2001-807XRAB

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WA

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[CBI Deleted] -- *Grant County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2001-807XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

OR (2)

OR

[CBI Deleted] -- Umatilla County/Province, OR, USA, 5 acres

[CBI Deleted] -- Umatilla County/Province, OR, USA, 3 acres

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-807XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

MONSANTO



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
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4700 River Rd.

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1. USDA Reference Number

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700 Chesterfield Parkway North

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4. Duration of Introduction

Interstate Movement and Release

January 12, 2002 - January 12, 2003

5. Recipient

Wheat, Triticum aestivum

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Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Variety: Bobwhite

Monsanto Reference ID

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Constructs: PV-TXGT10

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Promoter: CMP3/I5 -- [CBI Deleted]

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8. Introduction Interstate Movement and Release

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ORIGIN:

KS, MO, MT, OR, WA

DESTINATION:

KS, MO, MT, OR, WA

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

Monsanto Reference ID

2001-807XRAB

OR

[CBI Deleted] -- *Umatilla County/Province, OR, USA

[CBI Deleted] -- *Umatilla County/Province, OR, USA

WA

[CBI Deleted] -- *Benton County/Province, WA, USA

[CBI Deleted] -- *Grant County/Province, WA, USA

Monsanto Reference ID
2001-807XRAB

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

OR

[CBI Deleted] -- *Umatilla County/Province, OR, USA

Monsanto Reference ID
2001-807XRAB

[CBI Deleted] -- *Umatilla County/Province, OR, USA

WA

[CBI Deleted] -- *Benton County/Province, WA, USA

[CBI Deleted] -- *Grant County/Province, WA, USA

Monsanto Reference ID

2001-807XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

OR (2)

OR

[CBI Deleted] -- Umatilla County/Province, OR, USA, 5 acres

[CBI Deleted] -- Umatilla County/Province, OR, USA, 3 acres

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-807XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

December 17, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-348-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-348-13n	Applicant #:	2001-807XRAB
Received:	December 14, 2001	Effective:	January 13, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT OR WA		
Release destination:	OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008748

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

December 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-348-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-348-13n	Applicant #:	2001-807XRAB
Received:	December 14, 2001	Effective:	January 13, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT OR WA		
Release destination:	OR		

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Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008749

file copy

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

December 17, 2001

Dear Mr. Ames:

Enclosed is notification 01-348-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-348-13n	Applicant #:	2001-807XRAB
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Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008750

file copy

Mr. John Griesbach
Oregon Department of Agriculture
Plant Division
635 Capitol St., N.E.
Salem, OR 97310-0110

December 17, 2001

Dear Mr. Griesbach:

Enclosed is notification 01-348-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-348-13n	Applicant #:	2001-807XRAB
Received:	December 14, 2001	Effective:	January 13, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT OR WA		
Release destination:	OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008751

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

December 17, 2001

Dear Mr. Wessels:

Enclosed is notification 01-348-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-348-13n	Applicant #:	2001-807XRAB
Received:	December 14, 2001	Effective:	January 13, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT OR WA		
Release destination:	OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008752



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

December 17, 2001

Dear Mr. Brown:

Enclosed is notification 01-348-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-348-13n	Applicant #:	2001-807XRAB
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Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT OR WA		
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It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

Y State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E Brown

Signature: _____

(b) (6), (b) (7)(C)

Date: 12/31/01

State: MO

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_008753

DEC 31 2001



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

December 17, 2001

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

Dear Mr. Ames:

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(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 1/2/01

State: Montana

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Post-it
Fax Note
To MARY JACKSON
Fax# 301-734-8910
From DAN HILBURN
Phone# 503-986-4663

Date 1/7/02 # of pages 3

December 17, 2001

Mr. John Griesbach
Oregon Department of Agriculture
Plant Division
635 Capitol St., N.E.
Salem, OR 97310-0110

Dear Mr. Griesbach:

Enclosed is notification 01-348-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-348-13n Applicant #: 2001-807XRAB
Received: December 14, 2001 Effective: January 13, 2002
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MO MT OR WA
Release destination: OR

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Daniel J. Wilburn

Signature: (b) (6), (b) (7)(C)

Date: January 7, 2002

State: Oregon

Rptloc01/R4

* See additional conditions in 1/7/02 letter to Mary Jackson.



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_008755

JAN 7 2002



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

December 17, 2001

Dear Mr. Wessels:

Enclosed is notification 01-348-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-348-13n	Applicant #:	2001-807XRAB
Received:	December 14, 2001	Effective:	January 13, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT OR WA		
Release destination:	OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature

(b) (6), (b) (7)(C)

Date: 12/24/01

State: WA

Rptloc01/R4



January 8, 2002

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after January 13, 2002.

Interstate movement and Release

Notification no. 01-348-13n (2001-807XRAB)

Regulated article - Wheat

Destinations - Kansas, Missouri, Montana, Oregon, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, see additional conditions in the (attached) letter from the State of Oregon dated January 7, 2002.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Ames, Montana Dept. of Agric., Helena, MT
J. Griesbach, Oregon Dept. of Agric., Salem, OR
T. Wessels, Washington Dept. of Agric., Olympia, WA
File number 01-348-13n

OR120018_BR_008757



Oregon

John A. Kitzhaber, M.D., Governor

Department of Agriculture

635 Capitol Street NE
Salem, OR 97301-2532

January 7, 2002

Mary Jackson
Biotechnology Program Operations
Permits and Risk Assessments
USDA, APHIS, PPQ
4700 River Road
Riverdale, MD 20737



Dear Ms. Jackson:

We have received and reviewed notification number 01-348-13n. The notification was submitted by Monsanto for Glyphosate tolerant wheat. Due to an extremely sensitive market situation at the current time, we'd like to see stringent safeguards applied before this research proceeds in Oregon in 2002. We also suggest that given the current market climate around the world, USDA carefully review national requirements for research on genetically modified wheat. In particular, isolation distances designed to prevent mechanical mixing do not address pollen transfer concerns. Until tolerances for genetically modified wheat are established and accepted, protocols should reflect the need to ensure conventional wheat crops are completely free of contamination by genetically modified wheat.

Most of Oregon's wheat is grown for export and much of it goes to Japan. It is extremely important that we ensure that genetically modified wheat is fully segregated from Oregon's conventional commercial wheat crop. Inadvertent contamination of the conventional wheat crop would seriously constrain wheat grower's access to Japanese and other export markets. We suggest the following modifications to existing requirements to ensure that this 2002 research is done with the utmost concern for market preservation:

- 1.) Total acreage of plots is limited to 8.0 acres.
- 2.) Plots of genetically modified wheat must be separated from all other spring wheat by a distance of at least 660 ft.
- 3.) Plots of genetically modified wheat must be separated from non-spring wheat by a distance of at least 90 ft.
- 4.) Goatgrass (*Aegilops* sp.) must be eliminated from the area around the plots for a distance of at least 660 ft.
- 5.) Equipment used to plant and harvest the genetically modified wheat must be completely cleaned of all seeds and other plant parts on site before reuse.
- 6.) All parts of the genetically modified plants, including the seeds, must be destroyed on site. The plants must be sprayed with a labeled herbicide before plowing, flailing or other mechanical destruction.

7.) Plots must not be replanted into wheat in the year following planting of the genetically modified crop and the plots must be monitored for any volunteers. Volunteers must be destroyed.

8.) Either USDA must inspect the plots for isolation distance compliance and monitor the crop destruction process or the Oregon Department of Agriculture must be supplied with the information necessary to permit monitoring by ODA.

Thank you for helping us to make sure that this research does not interfere with the orderly marketing of Oregon's wheat crop. If you have any questions please don't hesitate to contact me.

Yours truly,

(b) (6), (b) (7)(C)

Daniel J. Hilburn
Administrator, Plant Division
(503) 986-4663

cc: (b) (6), (b) (7)(C) Monsanto

No CBI

2001 Wheat Field Test Report
USDA #01-348-13n **Monsanto #2001-807XRAB**

July 9, 2003

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147309341	Umatilla	OR	Not Planted
2147306779	Umatilla	OR	Not Planted

12/21/01 11:10 am

Notification Tracking Sheet

=====
Bp number: 01-352-05n
=====

App number: 2001-806XRAB
Received: 12/18/01
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 1/17/02
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 1/13/02
End movement: 1/13/03
Begin release: 1/13/02
End release: 1/13/03
Acre: 13.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--|-----------------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>ajd</i>] | [12/21/01] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>hnp</i>]* | [01/03/02]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KZD</i>] | [1/8/02]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg		
Interstate	*Dest*ID	*	*WR	*	[] []
Interstate	*Dest*KS	*	*SCR	*	[] []
Interstate	*Dest*MO	*	*SCR	*	[] []
Interstate	*Dest*MT	*	*WR	*	[] []
Interstate	*Dest*WA	*	*WR	*	[] []
Interstate	*Orig*ID	*	*WR	*	
Interstate	*Orig*KS	*	*SCR	*	
Interstate	*Orig*MO	*	*SCR	*	
Interstate	*Orig*MT	*	*WR	*	
Interstate	*Orig*WA	*	*WR	*	
Release	* *WA	*	3*WR	*	[] []

- | | | |
|--|----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>ajd</i>] | [1/3/02] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KZD</i>] | [1/15/02]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KZD</i>] | [1/16/02] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify | | |

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2001-806XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-352-05n

1. USDA Reference Number

2. Applicant Reference Number 2001-806XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

January 13, 2002 - January 13, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Variety: Bobwhite

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Monsanto Reference ID

2001-806XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID

2001-806XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

1000 Ship up to _300_____pounds wheat seed to and from each location.

ORIGIN:

ID, KS, MO, MT, WA

DESTINATION:

ID, KS, MO, MT, WA

Ship From:

ID

* (b) (4) Latah County/Province, ID (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

KS

* (b) (4) Sedgwick County/Province, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) Wichita, KS (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

* (b) (4) St. Louis County/Province, MO (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)
U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-806XRAB

MT

*[(b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

WA

*[(b) (4), (b) (6), (b) (7)(C) Adams County/Province, WA, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

*[(b) (4), (b) (6), (b) (7)(C) Grant County/Province, WA, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Whitman County/Province, WA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-806XRAB

*[(b) (4) Walla Walla County/Province, WA,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

Ship To:

ID
*[(b) (4) Latah County/Province, ID (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

KS
*[(b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

MO
*[(b) (4) St. Louis County/Province, MO, (b) (4) U.S.A.

CONFIDENTIAL

Monsanto Reference ID

2001-806XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)
U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MT

*[(b) (4)] Gallatin County/Province, MT (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

WA

*[(b) (4), (b) (6), (b) (7)(C)] Adams County/Province, WA (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4), (b) (6), (b) (7)(C)] Grant County/Province, WA (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-806XRAB

*[(b) (4) Whitman County/Province, WA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Walla Walla County/Province, WA,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-806XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (3)

WA

(b) (4), (b) (6), (b) (7)(C) Adams County/Province, WA, USA, 5 acres.
(b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C), USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4) Whitman County/Province, WA, USA, 3 acres.
(b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4) Walla Walla County/Province, WA,
USA, 5 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO



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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

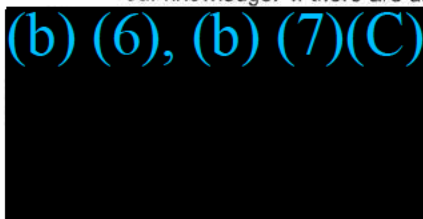
Monsanto Reference ID

2001-806XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description (referred to as vector components) category includes the names and information about genes and their expressed traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically,

information concerning marketing strategies, and the names of independent contractors participating in a

company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto.

Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-806XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-352-05n

1. USDA Reference Number

2. Applicant Reference Number 2001-806XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

January 13, 2002 - January 13, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Variety: Bobwhite

CBI-DELETED

Monsanto Reference ID

2001-806XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMOVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-806XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

1000 Ship up to _300_____pounds wheat seed to and from each location.

ORIGIN:

ID, KS, MO, MT, WA

DESTINATION:

ID, KS, MO, MT, WA

Ship From:

ID

[CBI Deleted] -- *Latah County/Province, ID, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID
2001-806XRAB

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

WA

[CBI Deleted] -- *Adams County/Province, WA, USA

[CBI Deleted] -- *Grant County/Province, WA, USA

[CBI Deleted] -- *Whitman County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID
2001-806XRAB

[CBI Deleted] -- *Walla Walla County/Province, WA, USA

Ship To:

ID

[CBI Deleted] -- *Latah County/Province, ID, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID
2001-806XRAB

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

WA

[CBI Deleted] -- *Adams County/Province, WA, USA

[CBI Deleted] -- *Grant County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID
2001-806XRAB

[CBI Deleted] -- *Whitman County/Province, WA, USA

[CBI Deleted] -- *Walla Walla County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID
2001-806XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (3)

WA

[CBI Deleted] -- Adams County/Province, WA, USA, 5 acres

[CBI Deleted] -- Whitman County/Province, WA, USA, 3 acres

[CBI Deleted] -- Walla Walla County/Province, WA, USA, 5 acres

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2001-806XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

MONSANTO

MONSANTO



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2001-806XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-352-05n

1. USDA Reference Number

2. Applicant Reference Number 2001-806XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

January 13, 2002 - January 13, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Variety: Bobwhite

Monsanto Reference ID

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Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

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GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

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Monsanto Reference ID

2001-806XRAB

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ORIGIN:

ID, KS, MO, MT, WA

DESTINATION:

ID, KS, MO, MT, WA

Ship From:

ID

[CBI Deleted] -- *Latah County/Province, ID, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

Monsanto Reference ID

2001-806XRAB

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

WA

[CBI Deleted] -- *Adams County/Province, WA, USA

[CBI Deleted] -- *Grant County/Province, WA, USA

[CBI Deleted] -- *Whitman County/Province, WA, USA

Monsanto Reference ID

2001-806XRAB

[CBI Deleted] -- *Walla Walla County/Province, WA, USA

Ship To:

ID

[CBI Deleted] -- *Latah County/Province, ID, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

Monsanto Reference ID
2001-806XRAB

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WA

[CBI Deleted] -- *Adams County/Province, WA, USA

[CBI Deleted] -- *Grant County/Province, WA, USA

Monsanto Reference ID
2001-806XRAB

[CBI Deleted] -- *Whitman County/Province, WA, USA

[CBI Deleted] -- *Walla Walla County/Province, WA, USA

Monsanto Reference ID

2001-806XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (3)

WA

[CBI Deleted] -- Adams County/Province, WA, USA, 5 acres

[CBI Deleted] -- Whitman County/Province, WA, USA, 3 acres

[CBI Deleted] -- Walla Walla County/Province, WA, USA, 5 acres

MONSANTO



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID
2001-806XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

file copy

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

December 21, 2001

Dear Dr. Vega:

Enclosed is notification 01-352-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-352-05n	Applicant #:	2001-806XRAB
Received:	December 18, 2001	Effective:	January 17, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(S)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008794

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

December 21, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-352-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-352-05n	Applicant #:	2001-806XRAB
Received:	December 18, 2001	Effective:	January 17, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008795

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

December 21, 2001

Dear Mr. Brown:

Enclosed is notification 01-352-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-352-05n	Applicant #:	2001-806XRAB
Received:	December 18, 2001	Effective:	January 17, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	WA		

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It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008796

file copy

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

December 21, 2001

Dear Mr. Ames:


Enclosed is notification 01-352-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-352-05n	Applicant #:	2001-806XRAB
Received:	December 18, 2001	Effective:	January 17, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,


Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008797

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

December 21, 2001

Dear Mr. Wessels:


Enclosed is notification 01-352-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-352-05n	Applicant #:	2001-806XRAB
Received:	December 18, 2001	Effective:	January 17, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,


Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008798



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

RECEIVED

December 21, 2001

JAN 09 2002

PLANT INDUSTRIES

Dear Dr. Vega:

Enclosed is notification 01-352-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-352-05n	Applicant #:	2001-806XRAB
Received:	December 18, 2001	Effective:	January 17, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

(b) (6), (b) (7)(C)

Date: Jan. 9, 2002

State: IDAHO

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

December 21, 2001

Dear Mr. Brown:

Enclosed is notification 01-352-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-352-05n Applicant #: 2001-806XRAB
Received: December 18, 2001 Effective: January 17, 2002
Institution: Monsanto Recipient: Wheat
Interstate destination: ID KS MO MT WA
Release destination: WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

 y

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 01/10/02

State: MO

Rptloc01/R4



APHIS - Protecting American Agriculture

OR120018_BR_006800 An Equal Opportunity Employer

JAN 11 2002

5737510005 P.09/13

DEPT OF AGRICULTURE

JAN-11-2002 10:17



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

December 21, 2001

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

Dear Mr. Ames:

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Bp number	01-352-05n	Applicant #:	2001-806XRAB
Received:	December 18, 2001	Effective:	January 17, 2002
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Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 1/14/02

State: Montana

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

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(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 1/10/02

State: WA

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_008802

JAN 10 2002

January 15, 2002

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after January 17, 2002.

Interstate movement and Release
Notification no. 01-352-05n (2001-806XRAB)
Regulated article - Wheat
Destinations - Idaho, Kansas, Missouri, Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

/s/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:

R. Vega, Idaho Dept. of Agric., Boise, ID
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Ames, Montana Dept. of Agric., Helena, MT
T. Wessels, Washington Dept. of Agric., Olympia, WA
File number 01-352-05n

OR120018_BR_008803

Confirmation Report-Memory Send

Time : Jan-15-02 05:47pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 740
Date : Jan-15 05:46pm
To : 916367377085
Document Pages : 01
Start time : Jan-15 05:46pm
End time : Jan-15 05:47pm
Pages sent : 01
Job number : 740

*** SEND SUCCESSFUL ***



Animal and
Plant Health
Inspection Service

Permits &
Risk
Assessments

4700 River Road, Unit 147
Riverdale, Maryland
20737-1235

January 15, 2002

(b) (6), (b) (7)(C)

Membrane Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after January 17, 2002.

Interstate movement and Release
Notification no. 01-352-05n (2001-806XRAB)
Regulated article - Wheat
Destinations - Idaho, Kansas, Missouri, Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:

A. Vega, Idaho Dept. of Agric., Boise, ID
T. Sam, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Ames, Montana Dept. of Agric., Helena, MT
T. Wessels, Washington Dept. of Agric., Olympia, WA



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_008804

CONFIDENTIAL

2001 Wheat Field Test Report
USDA #01-352-05n **Monsanto #2001-806XRAB**

July 9, 2003

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147306778	Adams	WA	Not Planted
2147306763	Whitman	WA	Not Planted
2147312318	Walla Walla	WA	

Walla Walla County/WA (2147312318)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2001 Wheat Field Test Report
USDA #01-352-05n Monsanto #2001-806XRAB

July 9, 2003

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147306778	Adams	WA	Not Planted
2147306763	Whitman	WA	Not Planted
2147312318	Walla Walla	WA	

Walla Walla County/WA (2147312318)

Planting Date: 04/02/2002

Harvest Date: 07/24/2002

Destruct Date: 07/25/2002

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

=====

Bp number: 01-353-18n

=====

App number: 2001-808XRAB
 Received: 12/19/01
 Institution: Monsanto
 Recipient: Wheat
 Status: Pending
 Effective date: 1/18/02
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: **(b) (6), (b) (7)(C)**
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: **(b) (6), (b) (7)(C)**
 Begin movement: 1/16/02
 End movement: 1/16/03
 Begin release: 1/16/02
 End release: 1/16/03
 Acre: 15.00
 CBI status: CBI
 Fax: 636-737-7085

- | | Initial | Date |
|--|--------------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>ajd</i>] | [12/21/01] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>AMK</i>]* | [1/3/02]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>K&D</i>] | [1/8/02]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*ID	*	*WR *
Interstate	*Dest*KS	*	*SCR *
Interstate	*Dest*MO	*	*SCR *
Interstate	*Dest*MT	*	*WR *
Interstate	*Dest*WA	*	*WR *
Interstate	*Orig*ID	*	*WR *
Interstate	*Orig*KS	*	*SCR *
Interstate	*Orig*MO	*	*SCR *
Interstate	*Orig*MT	*	*WR *
Interstate	*Orig*WA	*	*WR *
Release	* *ID	*	3*WR *

- | | | |
|--|--------------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>ajd</i>] | [1/3/02] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>K&D</i>] | [2/19/02]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>K&D</i>] | [2/20/02] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify | | |

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MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2001-808XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-353-18n

1. USDA Reference Number

2. Applicant Reference Number 2001-808XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

January 16, 2002 - January 16, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Variety: Bobwhite

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Monsanto Reference ID

2001-808XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [REDACTED]

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [REDACTED]

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID

2001-808XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

1000 Ship up to 300 pounds wheat seed to and from each location.

ORIGIN:

ID, KS, MO, MT, WA

DESTINATION:

ID, KS, MO, MT, WA

Ship From:

ID

*[(b) (4) Bannock County/Province,
ID, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

*[(b) (4) Latah County/Province, ID,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

*[(b) (4) Twin Falls County/Province, ID, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-808XRAB

*[(b) (4)] Latah County/Province, ID, (b) (4)
USAA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

KS

*[(b) (4)] Sedgwick County/Province, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b) (4)] St. Louis County/Province, MO, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)
U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MT

*[We (b) (4)] Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-808XRAB

WA

*[(b) (4) Benton County/Province, WA (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

*[(b) (4), (b) (6), (b) (7)(C) Grant County/Province, WA, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

Ship To:

ID

*[(b) (4) Bannock County/Province,
ID, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

*[(b) (4) Latah County/Province, ID,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-808XRAB

*[(b) (4) Twin Falls County/Province, ID, (b) (4) USA

CONTACT (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

*[(b) (4) Latah County/Province, ID, (b) (4) USAA

CONTACT (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

KS
*[(b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

MO
*[(b) (4) St. Louis County/Province, MO, (b) (4) U.S.A.

CONTACT (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-808XRAB

MT

*[(b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

WA

*[(b) (4) Benton County/Province, WA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

*[(b) (4), (b) (6), (b) (7)(C) Grant County/Province, WA, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-808XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (3)

ID

[(b) (4) Bannock County/Province,
ID, USA, 5 acres. (2147312700)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

[(b) (4) Latah County/Province, ID,
USA, 5 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

[(b) (4) Latah County/Province, ID, USAA,
5 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

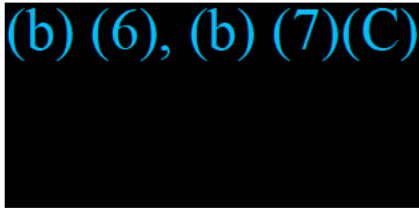
Monsanto Reference ID

2001-808XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2001-808XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-353-18n

1. USDA Reference Number

2. Applicant Reference Number 2001-808XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

January 16, 2002 - January 16, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Variety: Bobwhite

CBI-DELETED

Monsanto Reference ID

2001-808XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-808XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

1000 Ship up to 300 pounds wheat seed to and from each location.

ORIGIN:

ID, KS, MO, MT, WA

DESTINATION:

ID, KS, MO, MT, WA

Ship From:

ID

[CBI Deleted] -- *Bannock County/Province, ID, USA

[CBI Deleted] -- *Latah County/Province, ID, USA

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

CBI-DELETED

Monsanto Reference ID
2001-808XRAB

[CBI Deleted] -- *Latah County/Province, ID, USAA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2001-808XRAB

WA

[CBI Deleted] -- *Benton County/Province, WA, USA

[CBI Deleted] -- *Grant County/Province, WA, USA

Ship To:

ID

[CBI Deleted] -- *Bannock County/Province, ID, USA

[CBI Deleted] -- *Latah County/Province, ID, USA

CBI-DELETED

Monsanto Reference ID
2001-808XRAB

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

[CBI Deleted] -- *Latah County/Province, ID, USAA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2001-808XRAB

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

WA

[CBI Deleted] -- *Benton County/Province, WA, USA

[CBI Deleted] -- *Grant County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2001-808XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (3)

ID

[CBI Deleted] -- Bannock County/Province, ID, USA, 5 acres

[CBI Deleted] -- Latah County/Province, ID, USA, 5 acres

[CBI Deleted] -- Latah County/Province, ID, USAA, 5 acres

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>


Monsanto Reference ID

2001-808XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

MONSANTO



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2001-808XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-353-18n

1. USDA Reference Number

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3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

January 16, 2002 - January 16, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Variety: Bobwhite

Monsanto Reference ID

2001-808XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID

2001-808XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

1000 Ship up to 300 pounds wheat seed to and from each location.

ORIGIN:

ID, KS, MO, MT, WA

DESTINATION:

ID, KS, MO, MT, WA

Ship From:

ID

[CBI Deleted] -- *Bannock County/Province, ID, USA

[CBI Deleted] -- *Latah County/Province, ID, USA

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

Monsanto Reference ID
2001-808XRAB

[CBI Deleted] -- *Latah County/Province, ID, USAA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

Monsanto Reference ID
2001-808XRAB

WA

[CBI Deleted] -- *Benton County/Province, WA, USA

[CBI Deleted] -- *Grant County/Province, WA, USA

Ship To:

ID

[CBI Deleted] -- *Bannock County/Province, ID, USA

[CBI Deleted] -- *Latah County/Province, ID, USA

Monsanto Reference ID
2001-808XRAB

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

[CBI Deleted] -- *Latah County/Province, ID, USAA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

DELETED

Monsanto Reference ID

2001-808XRAB

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

WA

[CBI Deleted] -- *Benton County/Province, WA, USA

[CBI Deleted] -- *Grant County/Province, WA, USA

CBI DELETED

Monsanto Reference ID

2001-808XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (3)

ID

[CBI Deleted] -- Bannock County/Province, ID, USA, 5 acres

[CBI Deleted] -- Latah County/Province, ID, USA, 5 acres

[CBI Deleted] -- Latah County/Province, ID, USAA, 5 acres

MONSANTO



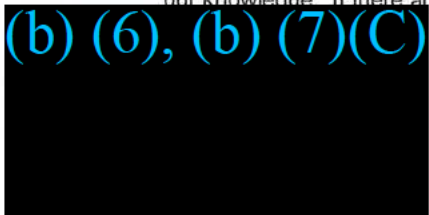
MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID
2001-808XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

file copy

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

December 21, 2001

Dear Dr. Vega:

Enclosed is notification 01-353-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-353-18n	Applicant #:	2001-808XRAB
Received:	December 19, 2001	Effective:	January 18, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

18
Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008841

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

December 21, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-353-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-353-18n	Applicant #:	2001-808XRAB
Received:	December 19, 2001	Effective:	January 18, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008842

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

December 21, 2001

Dear Mr. Brown:

Enclosed is notification 01-353-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-353-18n	Applicant #:	2001-808XRAB
Received:	December 19, 2001	Effective:	January 18, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008843

file copy

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

December 21, 2001

Dear Mr. Ames:

Enclosed is notification 01-353-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-353-18n	Applicant #:	2001-808XRAB
Received:	December 19, 2001	Effective:	January 18, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008844

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

December 21, 2001

Dear Mr. Wessels:


Enclosed is notification 01-353-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-353-18n	Applicant #:	2001-808XRAB
Received:	December 19, 2001	Effective:	January 18, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,


Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008845



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

RECEIVED

December 21, 2001

JAN 9 2002

PLANT INDUSTRIES

Dear Dr. Vega:

Enclosed is notification 01-353-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-353-18n	Applicant #:	2001-808XRAB
Received:	December 19, 2001	Effective:	January 18, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS MO MT WA		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION



State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

(b) (6), (b) (7)(C)

Date: Jan. 9, 2002

State: IDAHO

Rptloc01/R4



APHIS • Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_008846

JAN 9 2002



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

December 21, 2001

Dear Mr. Brown:

Enclosed is notification 01-353-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-353-18n	Applicant #:	2001-808XRAB
Received:	December 19, 2001	Effective:	January 18, 2002
Institution:	Monsanto	Recipient:	Wheat
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It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: _____

(b) (6), (b) (7)(C)

Date: 01/10/02

State: MO

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

FEB 19 2002

OR120018_BR_008847

TOTAL P.02



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

December 21, 2001

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

Dear Mr. Ames:

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Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

✓

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature

(b) (6), (b) (7)(C)

Date:

1/14/02

State:

Montana

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Rivardale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
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1111 Washington Street
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(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 1/10/02

State: WA

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_008849

JAN 10 2002

February 19, 2002

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 19, 2002.

Interstate movement and Release

Notification no. 01-353-18n (2001-808XRAB)

Regulated article - Wheat

Destination - Idaho, Kansas, Missouri, Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

/s/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:

R. Vega, Idaho Dept. of Agric., Boise, ID
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Ames, Montana Dept. of Agric., Helena, MT
T. Wessels, Washington Dept. of Agric., Olympia, WA
File number 01-353-18n

OR120018_BR_008850

Confirmation Report-Memory Send

Time : Feb-19-02 06:01pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 315
Date : Feb-19 06:00pm
To : 916367377085
Document Pages : 01
Start time : Feb-19 06:00pm
End time : Feb-19 06:01pm
Pages sent : 01
Job number : 315

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Permits &
Risk
Assessments

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

February 19, 2002

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

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G. Ames, Montana Dept. of Agric., Helena, MT
T. Weesels, Washington Dept. of Agric., Olympia, WA



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OR120018_BR_008851

CONFIDENTIAL

2001 Wheat Field Test Report
USDA #01-353-18n **Monsanto #2001-808XRAB**

August 5, 2003

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147312700	Bannock	ID	
2147312358	Latah	ID	Not Planted
2147312359	Latah	ID	Not Planted

Bannock County/ID (2147312700)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2001 Wheat Field Test Report
USDA #01-353-18n Monsanto #2001-808XRAB

August 5, 2003

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147312700	Bannock	ID	
2147312358	Latah	ID	Not Planted
2147312359	Latah	ID	Not Planted

Bannock County/ID (2147312700)

Planting Date: 05/03/2002

Harvest Date: 08/12/2002

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

1/16/02 9:33 am

Notification Tracking Sheet

=====
Bp number: 02-009-09n
=====

App number: 2002-98XRAB
Received: 1/09/02
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/08/02
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/07/02
End movement: 2/07/03
Begin release: 2/07/02
End release: 2/07/03
Acre: 1.00
CBI status: CBI

=====
Fax: 636-737-7085
=====

- | | Initial | Date |
|--|--------------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>ajb</i>] | [1/16/02] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>DSH</i>]* | [1/17/02]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>K&L</i>] | [1/22/02]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*CO	*	*WR *
Interstate	*Dest*KS	*	*SCR *
Interstate	*Dest*MO	*	*SCR *
Interstate	*Orig*CO	*	*WR *
Interstate	*Orig*KS	*	*SCR *
Interstate	*Orig*MO	*	*SCR *
Release	* *CO	*	1*WR *

- | | | |
|--|--------------------|-------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>ajb</i>] | [1/17/02] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>K&L</i>] | [2/7/02]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>K&L</i>] | [2/8/02] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify | | |

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2002-98XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-009-09n

1. USDA Reference Number

2. Applicant Reference Number 2002-98XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 07, 2002 - February 07, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Variety: Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2002-98XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/2 -

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

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Monsanto Reference ID

2002-98XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

2000 pounds of wheat grain may be shipped for the term of this notification Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

CO, KS, MO

DESTINATION:

CO, KS, MO

Ship From:

CO

*[(b) (4) Yuma County/Province, CO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

*[(b) (4) Arapaho County/Province, CO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

KS

*[(b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) , KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2002-98XRAB

MO

*(b) (4) St. Louis County/Province, MO (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO (b) (4), (b) (6), (b) (7)(C)
U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) St. Louis County/Province, MO (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

Ship To:

CO

*(b) (4) Yuma County/Province, CO (b) (4)
USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

] - CBI

*(b) (4) Arapaho County/Province, CO (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2002-98XRAB

KS

* [REDACTED] (b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)
USA, [REDACTED] (b) (4), (b) (6), (b) (7)(C), KS [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

* [REDACTED] (b) (4) St. Louis County/Province, MO, (b) (4) U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)
U.S.A., [REDACTED] (b) (4), (b) (6), (b) (7)(C), MO [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

* [REDACTED] (b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)
USA, [REDACTED] (b) (4), (b) (6), (b) (7)(C), MO, [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2002-98XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CO (1)

CO

[REDACTED] (b) (4) Yuma County/Province, CO, USA, 1
acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) CO (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

J - CBI

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

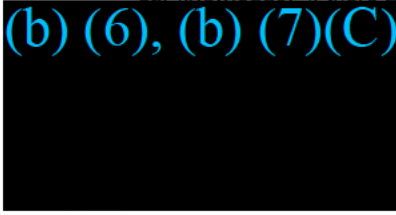
Monsanto Reference ID

2002-98XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Cirtical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2002-98XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-009-09n

1. USDA Reference Number

2. Applicant Reference Number 2002-98XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 07, 2002 - February 07, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Variety: Bobwhite

CBI-DELETED

Monsanto Reference ID

2002-98XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2002-98XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

2000 pounds of wheat grain may be shipped for the term of this notification Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

CO, KS, MO

DESTINATION:

CO, KS, MO

Ship From:

CO

[CBI Deleted] -- *Yuma County/Province, CO, USA

[CBI Deleted] -- *Arapaho County/Province, CO, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2002-98XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

[CBI Deleted] -- *St. Louis County/Province, MO, USA

Ship To:

CO

[CBI Deleted] -- *Yuma County/Province, CO, USA

[CBI Deleted] -- *Arapaho County/Province, CO, USA

CBI-DELETED

Monsanto Reference ID
2002-98XRAB

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

[CBI Deleted] -- *St. Louis County/Province, MO, USA

CBI-DELETED

Monsanto Reference ID

2002-98XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CO (1)

CO

[CBI Deleted] -- Yuma County/Province, CO, USA, 1 acres

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2002-98XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

MONSANTO



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID
2002-98XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

02-009-09n

1. **USDA Reference Number**
2. **Applicant Reference Number** 2002-98XRAB
3. **Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis MO 63198

Phone (b) (6), (b) (7)(C)
FAX 636/737-7085
Email (b) (6), (b) (7)(C)@monsanto.com

4. **Duration of Introduction**
Interstate Movement and Release February 07, 2002 - February 07, 2003

5. **Recipient**
Wheat, Triticum aestivum

6. **Regulated Article**
Phenotypic Category: HT
Phenotype: Glyphosate tolerant

Lines derived from Cultivar/Variety: Bobwhite

Monsanto Reference ID

2002-98XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID

2002-98XRAB

7. Mode of Transformation

Disarmed *Agrobacterium tumefaciens*

8. Introduction

Interstate Movement and Release

2000 pounds of wheat grain may be shipped for the term of this notification Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

CO, KS, MO

DESTINATION:

CO, KS, MO

Ship From:

CO

[CBI Deleted] -- *Yuma County/Province, CO, USA

[CBI Deleted] -- *Arapaho County/Province, CO, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

Monsanto Reference ID

2002-98XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

[CBI Deleted] -- *St. Louis County/Province, MO, USA

Ship To:

CO

[CBI Deleted] -- *Yuma County/Province, CO, USA

[CBI Deleted] -- *Arapaho County/Province, CO, USA

Monsanto Reference ID

2002-98XRAB

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

[CBI Deleted] -- *St. Louis County/Province, MO, USA

Monsanto Reference ID

2002-98XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CO (1)

CO

[CBI Deleted] -- Yuma County/Province, CO, USA, 1 acres

MONSANTO



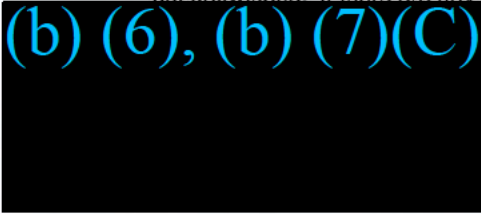
MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID
2002-98XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

file copy

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

January 16, 2002

Dear Mr. Yergert:

Enclosed is notification 02-009-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-009-09n	Applicant #:	2002-98XRAB
Received:	January 9, 2002	Effective:	February 8, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO KS MO		
Release destination:	CO		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008882

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 16, 2002

Dear Mr. Sim IV:

Enclosed is notification 02-009-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-009-09n	Applicant #:	2002-98XRAB
Received:	January 9, 2002	Effective:	February 8, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO KS MO		
Release destination:	CO		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008883

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 16, 2002

Dear Mr. Brown:

Enclosed is notification 02-009-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-009-09n	Applicant #:	2002-98XRAB
Received:	January 9, 2002	Effective:	February 8, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO KS MO		
Release destination:	CO		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(S)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008884



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

January 16, 2002

Dear Mr. Yergert:

Enclosed is notification 02-009-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-009-09n	Applicant #:	2002-98XRAB
Received:	January 9, 2002	Effective:	February 8, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO KS MO		
Release destination:	CO		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

 X State concurs with APHIS determination.

 State DOES NOT CONCUR and offers the following reasons:

Name of State official: MITCHELL YERGERT

Signature: (b) (6), (b) (7)(C)

Date: JAN. 28, 2002

State: COLORADO

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_008885

JAN 28 2002



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 16, 2002

Dear Mr. Brown:

Enclosed is notification 02-009-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-009-09n	Applicant #:	2002-98XRAB
Received:	January 9, 2002	Effective:	February 8, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO KS MO		
Release destination:	CO		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 1/25/02

State: MO

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_008886

JAN 28 2002

P.17/22 573751005

DEPT OF AGRICULTURE

JAN-28-2002 11:43

February 7, 2002

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 8, 2002.

Interstate movement and Release
Notification no. 02-009-09n (2002-98XRAB)
Regulated article - Wheat
Destinations - Colorado, Kansas, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

JS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:

M. Yergert, Colorado Dept. of Agric., Lakewood, CO
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
File number 02-009-09n

OR120018_BR_008887

Confirmation Report-Memory Send

Time : Feb-08-02 10:30am
Tel line 1 :
Tel line 2 :
Name :

Job number : 113
Date : Feb-08 10:28am
To : 916367377085
Document Pages : 01
Start time : Feb-08 10:28am
End time : Feb-08 10:29am
Pages sent : 01
Job number : 113

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Permits &
Risk
Assessments

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

February 7, 2002

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 8, 2002.

Interstate movement and Release
Notification no. 02-009-09n (2002-983RAB)
Regulated article - Wheat
Destinations - Colorado, Kansas, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:

M. Vergert, Colorado Dept. of Agric., Lakewood, CO
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept. of Agric., Jefferson City, MO



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_008888

CONFIDENTIAL

2002 Wheat Field Test Report
USDA #02-009-09n **Monsanto #2002-98XRAB**

August 1, 2003

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147313779	Yuma	CO

Yuma County/CO (2147313779)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2002 Wheat Field Test Report
USDA #02-009-09n **Monsanto #2002-98XRAB**

August 1, 2003

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147313779	Yuma	CO

Yuma County/CO (2147313779)

Planting Date: 02/22/2002

Harvest Date: 07/10/2002

Destruct Date: 07/10/2002

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

1/22/02 10:37 am

Notification Tracking Sheet

=====
Bp number: 02-018-19n
=====

App number: 2002-211XRAB
Received: 1/18/02
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/17/02
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: **(b) (6), (b) (7)(C)**
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: **(b) (6), (b) (7)(C)**
Begin movement: 2/15/02
End movement: 2/15/03
Begin release: 2/15/02
End release: 2/15/03
Acre: 6.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--|-------------------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>ajb</i>] | [1/22/02] |
| 2. <input type="checkbox"/> Review by biotechnologist | [<i>James White</i>]* | []* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KxN</i>] | [1/28/02]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*MO	*	*SCR *
Interstate	*Dest*WA	*	*WR *
Interstate	*Orig*MO	*	*SCR *
Interstate	*Orig*WA	*	*WR *
Release	* *WA	*	3*WR *

- | | | |
|--|----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>ajb</i>] | [1/23/02] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KxN</i>] | [2/14/02]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KxN</i>] | [2/15/02] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify | | |

MONSANTO



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MONSANTO COMPANY

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CHESTERFIELD, MISSOURI 63198
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FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2002-211XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-018-19n

1. USDA Reference Number

2. Applicant Reference Number 2002-211XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

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EEmail

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Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 15, 2002 - February 15, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Bobwhite

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Monsanto Reference ID

2002-211XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID

2002-211XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

200 pounds Ship up to __200____pounds wheat seed to and from each location.

ORIGIN:

MO, WA

DESTINATION:

MO, WA

Ship From:

MO

*[(b) (4) St. Louis County/Province, MO (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

WA

*[(b) (4) Whitman County/Province, WA,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Adams County/Province, WA, (b) (4)
Adams

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2002-211XRAB

*[(b) (4) Whitman County/Province, WA (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

Ship To:

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

WA

*[(b) (4) Whitman County/Province, WA,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Adams County/Province, WA, (b) (4)
Adams

CONFIDENTIAL

Monsanto Reference ID
2002-211XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Whitman County/Province, WA (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2002-211XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (3)

WA

[(b) (4) Whitman County/Province, WA, USA,
2 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4) Adams County/Province, WA, Adams,
2 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4) Whitman County/Province, WA, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) US, (b) (4), (b) (6), (b) (7)(C)

] - CBI

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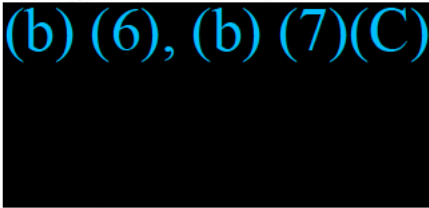
Monsanto Reference ID

2002-211XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



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CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector componets) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Cirtical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

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Monsanto Reference ID

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Permit Unit

USDA, APHIS, PPQ, BSS

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Riverdale, MD 27037

02-018-19n

1. USDA Reference Number

2. Applicant Reference Number 2002-211XRAB

3. Applicant/Responsible Party

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Phone

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FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 15, 2002 - February 15, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Bobwhite

CBI-DELETED

Monsanto Reference ID

2002-211XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2002-211XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

200 pounds Ship up to __200____pounds wheat seed to and from each location.

ORIGIN:

MO, WA

DESTINATION:

MO, WA

Ship From:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

WA

[CBI Deleted] -- *Whitman County/Province, WA, USA

[CBI Deleted] -- *Adams County/Province, WA, Adams

CBI-DELETED

Monsanto Reference ID
2002-211XRAB

[CBI Deleted] -- *Whitman County/Province, WA, USA

Ship To:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

WA

[CBI Deleted] -- *Whitman County/Province, WA, USA

[CBI Deleted] -- *Adams County/Province, WA, Adams

CBI-DELETED

Monsanto Reference ID
2002-211XRAB

[CBI Deleted] -- *Whitman County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2002-211XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (3)

WA

[CBI Deleted] -- Whitman County/Province, WA, USA, 2 acres

[CBI Deleted] -- Adams County/Province, WA, Adams, 2 acres

[CBI Deleted] -- Whitman County/Province, WA, USA, 2 acres

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CHESTERFIELD, MISSOURI 63198
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FAX (636) 737-7085
<http://www.monsanto.com>

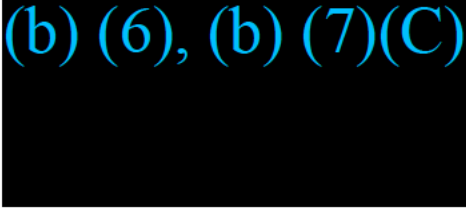
Monsanto Reference ID

2002-211XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



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Monsanto Reference ID
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Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

02-018-19n

1. USDA Reference Number
2. Applicant Reference Number 2002-211XRAB
3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis MO

63198

Phone
FAX
EMail

(b) (6), (b) (7)(C)

636/737-7085

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

February 15, 2002 - February 15, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Bobwhite

CBI-DELETED

Monsanto Reference ID

2002-211XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

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GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI Deleted

Monsanto Reference ID

2002-211XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

200 pounds Ship up to __200__ pounds wheat seed to and from each location.

ORIGIN:

MO, WA

DESTINATION:

MO, WA

Ship From:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

WA

[CBI Deleted] -- *Whitman County/Province, WA, USA

[CBI Deleted] -- *Adams County/Province, WA, Adams

CBI DELETED

Monsanto Reference ID
2002-211XRAB

[CBI Deleted] -- *Whitman County/Province, WA, USA

Ship To:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

WA

[CBI Deleted] -- *Whitman County/Province, WA, USA

[CBI Deleted] -- *Adams County/Province, WA, Adams

CBI-DELETED

Monsanto Reference ID
2002-211XRAB

[CBI Deleted] -- *Whitman County/Province, WA, USA

CBI Deleted

Monsanto Reference ID
2002-211XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (3)

WA

[CBI Deleted] -- Whitman County/Province, WA, USA, 2 acres

[CBI Deleted] -- Adams County/Province, WA, Adams, 2 acres

[CBI Deleted] -- Whitman County/Province, WA, USA, 2 acres

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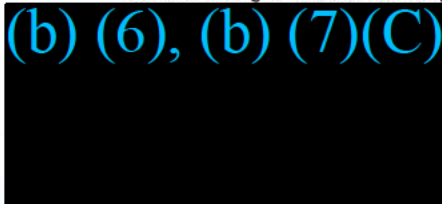
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Monsanto Reference ID
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9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 22, 2002

Dear Mr. Brown:

Enclosed is notification 02-018-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-018-19n	Applicant #:	2002-211XRAB
Received:	January 18, 2002	Effective:	February 17, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008919

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

January 22, 2002

Dear Mr. Wessels:

Enclosed is notification 02-018-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-018-19n	Applicant #:	2002-211XRAB
Received:	January 18, 2002	Effective:	February 17, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

JS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008920



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 22, 2002

Dear Mr. Brown:

Enclosed is notification 02-018-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number	02-018-19n	Applicant #:	2002-211XRAB
Received:	January 18, 2002	Effective:	February 17, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

 X State concurs with APHIS determination.

 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 01/31/02

State: MO

Rptloc01/R4



APHIS - Protecting American Agriculture

OR120018_BR_008921

An Equal Opportunity Employer

FEB 1 2002



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

January 22, 2002

Dear Mr. Wessels:

Enclosed is notification 02-018-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-018-19n	Applicant #:	2002-211XRAB
Received:	January 18, 2002	Effective:	February 17, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 2/5/02

State: WA

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_008922

FEB 5 2002

February 14, 2002

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 17, 2002.

Interstate movement and Release
Notification no. 02-018-19n (2002-211XRAB)
Regulated article - Wheat
Destinations - Missouri, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
T. Wessels, Washington Dept. of Agric., Olympia, WA
File number 02-018-19n

OR120018_BR_008923

Confirmation Report-Memory Send

Time : Feb-15-02 11:07am
Tel line 1 :
Tel line 2 :
Name :

Job number : 235
Date : Feb-15 11:06am
To : 916367377085
Document Pages : 01
Start time : Feb-15 11:06am
End time : Feb-15 11:07am
Pages sent : 01
Job number : 235

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Permits &
Risk
Assessments

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

February 14, 2002

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 17, 2002.

Interstate movement and release
Notification no. 02-018-19n (2002-211XRAB)
Regulated article - Wheat
Destinations - Missouri, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
T. Wessels, Washington Dept. of Agric., Olympia, WA



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_008924

MONSANTO



February 22, 2002

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

Ms. Mary Jackson
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Jackson:

In reviewing Monsanto's acknowledged wheat notification, it was discovered an incorrect amount of acreage was requested. We requested 2 acres for each release site it should have been 4 acres. The notification is Monsanto number 2001-211XRAB, USDA number 02-018-19n.

I apologize for any inconvenience this may cause. Please call me at (b) (6), (b) (7)(C) if you have any questions.

Sincerely,

(b) (6), (b) (7)(C)

cc: T. Wessels, Plant Services, Olympia, WA
R. Stoaks, USDA, APHIS, PPQ, Fort Collins, CO

OR120018_BR_008925

CONFIDENTIAL

2002 Wheat Field Test Report
USDA #02-018-19n **Monsanto #2002-211XRAB**

August 5, 2003

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147307638	Whitman	WA	Not Planted
2147314278	Adams	WA	
2147306763	Whitman	WA	

Adams County/WA (2147314278)

(b) (4)

(b) (4)

Whitman County/WA (2147306763)

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2002 Wheat Field Test Report
USDA #02-018-19n Monsanto #2002-211XRAB

August 5, 2003

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147307638	Whitman	WA	Not Planted
2147314278	Adams	WA	
2147306763	Whitman	WA	

Adams County/WA (2147314278)

Planting Date: 04/05/2002

Harvest Date: 07/26/2002

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Whitman County/WA (2147306763)

Planting Date: 05/02/2002

Harvest Date: 09/12/2002

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

1/30/02 8:23 am

Notification Tracking Sheet

=====

Bp number: 02-022-57n

=====

App number: 2002-256XRAB
Received: 1/22/02
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/21/02
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: **(b) (6), (b) (7)(C)**
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: **(b) (6), (b) (7)(C)**
Begin movement: 2/20/02
End movement: 2/20/03
Begin release: 2/20/02
End release: 2/20/03
Acre: 114.00
CBI status: CBI
Fax: 636-737-7085

- =====
- | | Initial | Date |
|--|-----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>apl</i>] | [1/30/02] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>hnp</i>]* | [1/31/02]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>Kxro</i>] | [2/6/02]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg		
Interstate	*Dest*	KS	*	*SCR	*
Interstate	*Dest*	MO	*	*SCR	*
Interstate	*Dest*	MT	*	*WR	*
Interstate	*Dest*	ND	*	*SCR	*
Interstate	*Dest*	SD	*	*SCR	*
Interstate	*Orig*	KS	*	*SCR	*
Interstate	*Orig*	MO	*	*SCR	*
Interstate	*Orig*	MT	*	*WR	*
Interstate	*Orig*	ND	*	*SCR	*
Interstate	*Orig*	SD	*	*SCR	*
Release	*	*ND	*	15*SCR	*

- | | | |
|--|-----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>apl</i>] | [1/31/02] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>Kxro</i>] | [3/15/02]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>Kxro</i>] | [3/20/02] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,
Ph category, Phenotype, Gene, Donor, Marker,
Does not qualify | | |

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID
2002-256XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-022-57n

1. USDA Reference Number

2. Applicant Reference Number 2002-256XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E Mail

(b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 20, 2002 - February 20, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Hybrid: Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2002-256XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [REDACTED]

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [REDACTED]

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2002-256XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

A total of 5000 pounds of seed may be shipped for the term of this Notification. Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

KS, MO, MT, ND, SD

DESTINATION:

KS, MO, MT, ND, SD

Ship From:

KS

*[(b) (4) Sedgwick County/Province, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MT

*[(b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2002-256XRAB

ND

*[

(b) (4)

USA

(b) (4)

Williams County/Province, ND,

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

ND,

(b) (4), (b) (6), (b) (7)(C)

USA,

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

*[

(b) (4), (b) (6), (b) (7)(C)

Cass County/Province, ND,

(b) (4), (b) (6), (b) (7)(C)

USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ND,

(b) (4), (b) (6), (b) (7)(C)

USA,

] - CBI

*[

(b) (4), (b) (6), (b) (7)(C)

La Moure County/Province, ND,

(b) (4), (b) (6), (b) (7)(C)

USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ND,

(b) (4), (b) (6), (b) (7)(C)

USA,

] - CBI

*[

(b) (4), (b) (6), (b) (7)(C)

Cass County/Province, ND,

(b) (4), (b) (6), (b) (7)(C)

USA

CONTACT:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ND,

(b) (4), (b) (6), (b) (7)(C)

USA,

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2002-256XRAB

*[(b) (4), (b) (6), (b) (7)(C) Burke County/Province, ND, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

*[(b) (4), (b) (6), (b) (7)(C) Wells County/Province, ND, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

*[(b) (4) Burke County/Province, ND, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

*[(b) (4) Fargo, Cass County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2002-256XRAB

*[(b) (4) Foster County/Province, ND,
(b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.

] - CBI

*[(b) (4) Ward County/Province, ND, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.

] - CBI

*[(b) (4) Cass County/Province, ND, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) U.S.A., ND,

] - CBI

*[(b) (4) (b) (4) Cass County/Province, ND,
(b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2002-256XRAB

*[(b) (4) , Cass County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Cass County/Province, ND, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)
ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Cass County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Cass
County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

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Monsanto Reference ID
2002-256XRAB

*[(b) (4) Cavalier
County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

* (b) (4), (b) (6), (b) (7)(C) Mountrail County/Province, ND, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

*[(b) (4) Mountrail County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

SD

*[(b) (4) Brookings County/Province, SD,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

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Monsanto Reference ID
2002-256XRAB

Ship To:

KS

*[(b) (4) Wichita, Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MT

*[(b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

ND

*[(b) (4) Williams County/Province, ND,
(b) (4) USA

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Monsanto Reference ID
2002-256XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

*[(b) (4), (b) (6), (b) (7)(C) La Moure County/Province, ND, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

*[(b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2002-256XRAB

*[(b) (4), (b) (6), (b) (7)(C) Burke County/Province, ND (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

*[(b) (4), (b) (6), (b) (7)(C) Wells County/Province, ND (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

*[(b) (4) Burke County/Province, ND (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

*[(b) (4) Cass County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2002-256XRAB

*[(b) (4) Foster County/Province, ND,
(b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Ward County/Province, ND, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Cass County/Province, ND, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C) ND,

] - CBI

*[(b) (4) Cass County/Province, ND,
(b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2002-256XRAB

*[(b) (4) Cass County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Cass County/Province, ND, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)
ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Cass County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Cass
County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2002-256XRAB

*[(b) (4) Cavalier
County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4), (b) (6), (b) (7)(C) Mountrail County/Province, ND, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

*[(b) (4) Mountrail County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.,

] - CBI

SD

*[(b) (4) (b) (4)
(b) (4) USA, Brookings County/Province, SD,

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

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Monsanto Reference ID

2002-256XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (15)

ND

[(b) (4) Williams County/Province, ND, USA, 5 acres. (-896470389)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND, USA, 10 acres. (b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C) La Moure County/Province, ND, USA, 10 acres. (b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND, USA, 10 acres. (b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2002-256XRAB

(b) (4), (b) (6), (b) (7)(C) Burke County/Province, ND, USA, 3 acres.
(b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C) Wells County/Province, ND, USA, 10 acres. (b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4) Foster County/Province, ND, U.S.A., 10 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4) Ward County/Province, ND, U.S.A., 5 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

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Monsanto Reference ID
2002-256XRAB

[(b) (4) Cass County/Province, ND, 10 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

[(b) (4) Cass County/Province, ND, USA, 10 acres.
(2147307378)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

[(b) (4) Cass County/Province, ND, USA, 10 acres.
(2147303287)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

[(b) (4) Cass County/Province,
ND, USA, 5 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2002-256XRAB

(b) (4)
County/Province, ND, USA, 10 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C) Mountrail County/Province, ND, USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4) (b) (4) Mountrail County/Province, ND, USA, 3 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

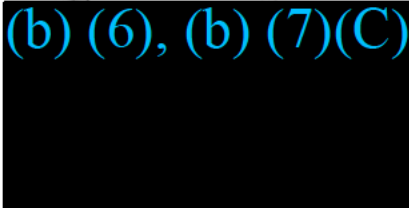
Monsanto Reference ID

2002-256XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C. Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C. Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C. Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Cirtical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2002-256XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-022-57n

1. USDA Reference Number

2. Applicant Reference Number 2002-256XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 20, 2002 - February 20, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Hybrid: Bobwhite

CBI-DELETED

Monsanto Reference ID

2002-256XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2002-256XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

A total of 5000 pounds of seed may be shipped for the term of this Notification Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

KS, MO, MT, ND, SD

DESTINATION:

KS, MO, MT, ND, SD

Ship From:**KS**

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2002-256XRAB

ND

[CBI Deleted] -- *Williams County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *La Moure County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID
2002-256XRAB

[CBI Deleted] -- *Burke County/Province, ND, USA

[CBI Deleted] -- *Wells County/Province, ND, USA

[CBI Deleted] -- *Burke County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID
2002-256XRAB

[CBI Deleted] -- *Foster County/Province, ND, U.S.A.

[CBI Deleted] -- *Ward County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, U.S.A.

CBI-DELETED

Monsanto Reference ID
2002-256XRAB

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID
2002-256XRAB

[CBI Deleted] -- *Cavalier County/Province, ND, USA

[CBI Deleted] -- *Mountrail County/Province, ND, USA

[CBI Deleted] -- *Mountrail County/Province, ND, USA

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID

2002-256XRAB

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

ND

[CBI Deleted] -- *Williams County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID
2002-256XRAB

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *La Moure County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID
2002-256XRAB

[CBI Deleted] -- *Burke County/Province, ND, USA

[CBI Deleted] -- *Wells County/Province, ND, USA

[CBI Deleted] -- *Burke County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID
2002-256XRAB

[CBI Deleted] -- *Foster County/Province, ND, U.S.A.

[CBI Deleted] -- *Ward County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, U.S.A.

CBI-DELETED

Monsanto Reference ID
2002-256XRAB

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID

2002-256XRAB

[CBI Deleted] -- *Cavalier County/Province, ND, USA

[CBI Deleted] -- *Mountrail County/Province, ND, USA

[CBI Deleted] -- *Mountrail County/Province, ND, USA

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID

2002-256XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (15)

ND

[CBI Deleted] -- Williams County/Province, ND, USA, 5 acres

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres

[CBI Deleted] -- La Moure County/Province, ND, USA, 10 acres

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres

CBI-DELETED

Monsanto Reference ID

2002-256XRAB

[CBI Deleted] -- Burke County/Province, ND, USA, 3 acres

[CBI Deleted] -- Wells County/Province, ND, USA, 10 acres

[CBI Deleted] -- Foster County/Province, ND, U.S.A., 10 acres

[CBI Deleted] -- Ward County/Province, ND, U.S.A., 5 acres

[CBI Deleted] -- Cass County/Province, ND, 10 acres

CBI-DELETED

Monsanto Reference ID
2002-256XRAB

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres

[CBI Deleted] -- Cass County/Province, ND, USA, 5 acres

[CBI Deleted] -- Cavalier County/Province, ND, USA, 10 acres

CBI-DELETED

Monsanto Reference ID
2002-256XRAB

[CBI Deleted] -- Mountrail County/Province, ND, USA, 3 acres

[CBI Deleted] -- Mountrail County/Province, ND, USA, 3 acres

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

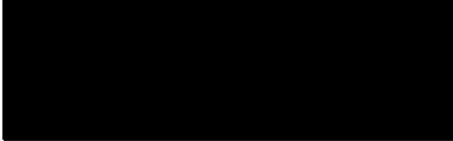
Monsanto Reference ID

2002-256XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

MONSANTO



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2002-256XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-022-57n

1. USDA Reference Number

2. Applicant Reference Number 2002-256XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 20, 2002 - February 20, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Hybrid: Bobwhite

Monsanto Reference ID

2002-256XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID

2002-256XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

A total of 5000 pounds of seed may be shipped for the term of this Notification Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

KS, MO, MT, ND, SD

DESTINATION:

KS, MO, MT, ND, SD

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

Monsanto Reference ID

2002-256XRAB

ND

[CBI Deleted] -- *Williams County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *La Moure County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

Monsanto Reference ID
2002-256XRAB

[CBI Deleted] -- *Burke County/Province, ND, USA

[CBI Deleted] -- *Wells County/Province, ND, USA

[CBI Deleted] -- *Burke County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, USA

Monsanto Reference ID

2002-256XRAB

[CBI Deleted] -- *Foster County/Province, ND, U.S.A.

[CBI Deleted] -- *Ward County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, U.S.A.

Monsanto Reference ID
2002-256XRAB

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

Monsanto Reference ID
2002-256XRAB

[CBI Deleted] -- *Cavalier County/Province, ND, USA

[CBI Deleted] -- *Mountrail County/Province, ND, USA

[CBI Deleted] -- *Mountrail County/Province, ND, USA

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

Monsanto Reference ID
2002-256XRAB

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

ND

[CBI Deleted] -- *Williams County/Province, ND, USA

Monsanto Reference ID
2002-256XRAB

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *La Moure County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

Monsanto Reference ID

2002-256XRAB

[CBI Deleted] -- *Burke County/Province, ND, USA

[CBI Deleted] -- *Wells County/Province, ND, USA

[CBI Deleted] -- *Burke County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, USA

Monsanto Reference ID

2002-256XRAB

[CBI Deleted] -- *Foster County/Province, ND, U.S.A.

[CBI Deleted] -- *Ward County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, U.S.A.

Monsanto Reference ID

2002-256XRAB

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

Monsanto Reference ID

2002-256XRAB

[CBI Deleted] -- *Cavalier County/Province, ND, USA

[CBI Deleted] -- *Mountrail County/Province, ND, USA

[CBI Deleted] -- *Mountrail County/Province, ND, USA

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

Monsanto Reference ID

2002-256XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (15)

ND

[CBI Deleted] -- Williams County/Province, ND, USA, 5 acres

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres

[CBI Deleted] -- La Moure County/Province, ND, USA, 10 acres

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres

Monsanto Reference ID

2002-256XRAB

[CBI Deleted] -- Burke County/Province, ND, USA, 3 acres

[CBI Deleted] -- Wells County/Province, ND, USA, 10 acres

[CBI Deleted] -- Foster County/Province, ND, U.S.A., 10 acres

[CBI Deleted] -- Ward County/Province, ND, U.S.A., 5 acres

[CBI Deleted] -- Cass County/Province, ND, 10 acres

Monsanto Reference ID
2002-256XRAB

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres

[CBI Deleted] -- Cass County/Province, ND, USA, 5 acres

[CBI Deleted] -- Cavalier County/Province, ND, USA, 10 acres

Monsanto Reference ID
2002-256XRAB

[CBI Deleted] -- Mountrail County/Province, ND, USA, 3 acres

[CBI Deleted] -- Mountrail County/Province, ND, USA, 3 acres

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Reference ID

2002-256XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 30, 2002

Dear Mr. Sim IV:

Enclosed is notification 02-022-57n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-57n	Applicant #:	2002-256XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_008993

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 30, 2002

Dear Mr. Brown:

Enclosed is notification 02-022-57n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-57n	Applicant #:	2002-256XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008994

file copy

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 30, 2002

Dear Mr. Ames:

Enclosed is notification 02-022-57n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-57n	Applicant #:	2002-256XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008995

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

January 30, 2002

Dear Mr. Nelson:

Enclosed is notification 02-022-57n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-57n	Applicant #:	2002-256XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008996

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

January 30, 2002

Dear Mr. Fridley:

Enclosed is notification 02-022-57n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-57n	Applicant #:	2002-256XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008997



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 30, 2002

Dear Mr. Brown:

Enclosed is notification 02-022-57n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-022-57n Applicant #: 2002-256XRAB
Received: January 22, 2002 Effective: February 21, 2002
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MO MT ND SD
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

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Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 02/15/02

State: MO

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_008998

FEB 20 2002



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 30, 2002

Dear Mr. Ames:

Enclosed is notification 02-022-57n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-57n	Applicant #:	2002-256XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, FPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

✓

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 2/7/02

State: Montana

RptLoc01/R4



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OR120018_BR_008999

FEB 7 2002



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

release

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

January 30, 2002

Dear Mr. Nelson:

Enclosed is notification 02-022-57n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-022-57n Applicant #: 2002-256XRAB
Received: January 22, 2002 Effective: February 21, 2002
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MO MT ND SD
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

1 State concurs with APHIS determination. *to attach conditions*

State DOES NOT CONCUR and offers the following reasons:

Name of State official: *David R. Nelson*

Signature: (b) (6), (b) (7)(C)

Date: *2-28-02*

State: *ND*

Rptloc01/R4



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OR120018_BR_009000

MAR 15 2002



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737



January 30, 2002

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

Dear Mr. Fridley:

Enclosed is notification 02-022-57n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number 02-022-57n Applicant #: 2002-256KRAB
Received: January 22, 2002 Effective: February 21, 2002
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MO MT ND SD
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 2/11/02

State: South Dakota

Rpt1loc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_009001

FEB 14 2002

March 15, 2002

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 15, 2002.

Interstate movement and Release

Notification no. 02-022-57n (2002-256XRAB)

Regulated article - Wheat

Destinations - Kansas, Missouri, Montana, North Dakota, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of North Dakota has (attached) modification of conditions for release of wheat.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

CC:

T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Ames, Montana Dept. of Agric., Helena, MT
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
File number 02-022-57n

OR120018_BR_009002

AGRICULTURE COMMISSIONER
ROGER JOHNSON



PHONE (701) 328-2231
(800) 242-7535
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE
State of North Dakota
600 E. Boulevard Ave. Dept. 602
Bismarck, ND 58505-0020

TO: Mary Jackson
Biotechnology Program Operations – Permit Unit
USDA APHIS
4700 River Road
Riverdale MD 27037
FROM: David R. Nelson
DATE: March 27, 2002
RE: Modification of Conditions for Release of Wheat
02-022-59n
02-051-19n
02-046-30n
02-022-57n

(b) (6), (b) (7)(C)

Following further discussions with Monsanto we are making a slight modification in the conditions for release of the wheat notifications listed above.

North Dakota Supplemental Conditions 2002

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
3. Because of the possibility of volunteers:
 - Wheat should not be grown within the field trial area nor within 33 feet of the field trial area during the subsequent growing season and any wheat volunteers appearing within this area should be destroyed prior to flowering.
 - If wheat grown for harvest as grain is grown within 330 feet of the field trial during the year of the field trial, then wheat intended for use as seed should not be grown within this area during the following year.

cc (b) (6), (b) (7)(C) Monsanto

OR120018_BR_009003

AGRICULTURE COMMISSIONER
ROGER JOHNSON



PHONE (701) 328-2231
(800) 242-7535
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE
State of North Dakota
600 E. Boulevard Ave. Dept. 602
Bismarck, ND 58505-0020

TO: Mary Jackson
USDA-APHIS-PPQ
Permits-Biotechnology
4700 River Road
Riverdale MD 20737

FROM: David R. Nelson

(b) (6), (b) (7)(C)

DATE: February 28, 2002

RE: Bp number 02-022-57n

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat appearing within this area should be destroyed.

OR120018_BR_009004

Confirmation Report-Memory Send

Time : Mar-19-02 04:54pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 049
Date : Mar-19 04:53pm
To : 916367377085
Document Pages : 02
Start time : Mar-19 04:53pm
End time : Mar-19 04:54pm
Pages sent : 02
Job number : 049

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Permits &
Risk
Assessments

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

March 15, 2002

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 15, 2002.

Interstate movement and Release
Notification no. 02-022-57n (2002-256IRAB)
Regulated article - Wheat
Destinations - Kansas, Missouri, Montana, North Dakota, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of North Dakota has (attached) conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
C. Ames, Montana Dept. of Agric., Helena, MT
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD



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OR120018_BR_009005

CONFIDENTIAL

2002 Wheat Field Test Report
USDA #02-022-57n **Monsanto #2002-256XRAB**

September 19, 2003

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
-896470389	Williams	ND	Not Planted
2147307361	Cass	ND	
2147307363	La Moure	ND	Not Planted
2147314745	Cass	ND	
2147307368	Burke	ND	
2147307365	Wells	ND	Not Planted
1611677957	Foster	ND	
2147310478	Ward	ND	Not Planted
76481322	Cass	ND	Not Planted
2147307378	Cass	ND	
2147303287	Cass	ND	
2147314640	Cass	ND	Not Planted
2147307343	Cavalier	ND	
2147314642	Mountrail	ND	Not Planted
2147303521	Mountrail	ND	Not Planted

Cass County/ND (2147307361)

(b) (4)

(b) (4)

Cass County/ND (2147314745)

(b) (4)

(b) (4)

Burke County/ND (2147307368)

(b) (4)

(b) (4)

Foster County/ND (1611677957)

(b) (4)

(b) (4)

Cass County/ND (2147307378)

(b) (4)

Cass County/ND (2147303287)

(b) (4)

(b) (4)

Cavalier County/ND (2147307343)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2002 Wheat Field Test Report
USDA #02-022-57n Monsanto #2002-256XRAB

September 19, 2003

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
-896470389	Williams	ND	Not Planted
2147307361	Cass	ND	
2147307363	La Moure	ND	Not Planted
2147314745	Cass	ND	
2147307368	Burke	ND	
2147307365	Wells	ND	Not Planted
1611677957	Foster	ND	
2147310478	Ward	ND	Not Planted
76481322	Cass	ND	Not Planted
2147307378	Cass	ND	
2147303287	Cass	ND	
2147314640	Cass	ND	Not Planted
2147307343	Cavalier	ND	
2147314642	Mountrail	ND	Not Planted
2147303521	Mountrail	ND	Not Planted

Cass County/ND (2147307361)

Planting Date: 05/20/2002

Harvest Date: 09/04/2002

Destruct Date: 09/14/2002

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Cass County/ND (2147314745)

Planting Date: 05/19/2002

Harvest Date: 09/05/2002

Destruct Date: 09/14/2002

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Burke County/ND (2147307368)

Planting Date: 05/26/2002

Harvest Date: 09/17/2002

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Foster County/ND (1611677957)

Planting Date: 05/14/2002

Harvest Date: 09/06/2002

Destruct Date: 09/06/2002

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Cass County/ND (2147307378)

Planting Date: 05/14/2002

Harvest Date: 09/04/2002

Destruct Date: 09/04/2002

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Cass County/ND (2147303287)

Planting Date: 05/07/2002

Destruct Date: 07/30/2002

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Cavalier County/ND (2147307343)

Planting Date: 05/16/2002

Harvest Date: 09/13/2002

Destruct Date: 09/16/2002

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
<http://www.monsanto.com>

April 7, 2004

Mr. Juan A. Roman
Team Leader
Permitting and Notification
USDA, APHIS
4700 River Road, Unit 147
Riverdale, MD 20737

Dear Mr. Roman:

I would like to inform you of a change in the farm (or company) name and/or address for the approved notifications:

<u>USDA#</u>	<u>Monsanto#</u>
02-022-57n	2002-256XRAB
02-051-19n	2002-457XRAB
03-015-10n	2003-22XRAB
03-052-27n	2003-205XRAB
04-021-05n	2004-36XRAB

The former name/address information is:

(b) (4)

The new name/address information is:

(b) (4)

If you have any questions, please contact me at (b) (7)(C), (b) (6)

Sincerely yours,

(b) (7)(C), (b) (6)

Cc: (b) (6), (b) (7)(C)

OR120018_BR_009020

MONSANTO



CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
<http://www.monsanto.com>

April 7, 2004

Mr. Juan A. Roman
Team Leader
Permitting and Notification
USDA, APHIS
4700 River Road, Unit 147
Riverdale, MD 20737

Dear Mr. Roman:

I would like to inform you of a change in the farm (or company) name and/or address for the approved notifications:

<u>USDA#</u>	<u>Monsanto#</u>
02-022-57n	2002-256XRAB
02-051-19n	2002-457XRAB
03-015-10n	2003-22XRAB
03-052-27n	2003-205XRAB
04-021-05n	2004-36XRAB

The former name/address information is:
[CBI DELETED] - Cavalier, ND

The new name/address information is:
[CBI DELETED] - Cavalier, ND

If you have any questions, please contact me at (b) (7)(C), (b) (6)

Sincerely yours,

(b) (7)(C), (b) (6)

Cc: (b) (6), (b) (7)(C)

OR120018_BR_009021

1/30/02 8:23 am

Notification Tracking Sheet

=====
Bp number: 02-022-58n
=====

App number: 2002-257XRAB
Received: 1/22/02
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/21/02
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (7)(C), (b) (6)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (7)(C), (b) (6)
Begin movement: 2/20/02
End movement: 2/20/03
Begin release: 2/20/02
End release: 2/20/03
Acre: 10.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--|-----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>apd</i>] | [1/30/02] |
| 2. <input type="checkbox"/> Review by biotechnologist | [<i>hrp</i>]* | [1/31/02]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KX10</i>] | [2/6/02]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*	KS	*SCR *
Interstate	*Dest*	MO	*SCR *
Interstate	*Dest*	MT	*WR *
Interstate	*Dest*	SD	*SCR *
Interstate	*Orig*	KS	*SCR *
Interstate	*Orig*	MO	*SCR *
Interstate	*Orig*	MT	*WR *
Interstate	*Orig*	SD	*SCR *
Release	*	SD	* 2*SCR *

- | | | |
|--|-----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>apd</i>] | [1/31/02] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KX10</i>] | [2/21/02]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KX10</i>] | [2/26/02] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify | | |

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FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2002-257XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-022-58n

1. USDA Reference Number

2. Applicant Reference Number 2002-257XRAB

3. Applicant/Responsible Party

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700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 20, 2002 - February 20, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Hybrid: Bobwhite

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Monsanto Reference ID

2002-257XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID
2002-257XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 3000 pounds of seed may be shipped for the term of this Notification Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

KS, MO, MT, SD

DESTINATION:

KS, MO, MT, SD

Ship From:

KS

* [REDACTED] (b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C)
USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

* [REDACTED] (b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)
USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

MT

* [REDACTED] (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2002-257XRAB

SD

* (b) (4), (b) (6), (b) (7)(C) Spink County/Province, SD, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD,
(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

* (b) (4) Minnehaha County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD,
(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

* (b) (4) Brookings County/Province, SD, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C)
U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

* (b) (4) Brookings County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2002-257XRAB

*[(b) (4)] Codington
County/Province, SD (b) (4) USA

CONTACT (b) (4), (b) (6), (b) (7)(C)
U.S.A. (b) (4), (b) (6), (b) (7)(C) SD (b) (4), (b) (6), (b) (7)(C)

] - CBI

Ship To:

KS

*[(b) (4)] edgwick County/Province, KS (b) (4) USA

CONTACT (b) (4), (b) (6), (b) (7)(C)
USA (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b) (4)] St. Louis County/Province, MO, (b) (4) USA

CONTACT (b) (4), (b) (6), (b) (7)(C)
USA (b) (4), (b) (6), (b) (7)(C) MO (b) (4), (b) (6), (b) (7)(C)

] - CBI

MT

*[(b) (4)] Gallatin County/Province, MT, (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID
2002-257XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

SD

*[(b) (4), (b) (6), (b) (7)(C) Spink County/Province, SD, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) Sioux Falls, SD,
(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Minnehaha County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD,
(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Brookings County/Province, SD, (b) (4) U.S.A

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C)
U.S.A, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2002-257XRAB

*(b) (4) (b) (4) Brookings County/Province, SD,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

*(b) (4) (b) (4) Codington
County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
U.S. (b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2002-257XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (2)

SD

[(b) (4), (b) (6), (b) (7)(C) Spink County/Province, SD, USA, 5 acres. (b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

[(b) (4)
County/Province, SD, USA, 5 acres. (b) (4) Codington

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

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MONSANTO COMPANY

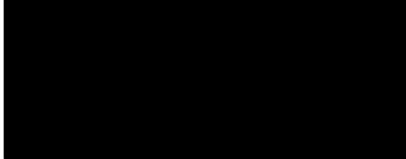
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PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID
2002-257XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C. Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C. Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C. Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

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Monsanto Reference ID

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Permit Unit

USDA, APHIS, PPQ, BSS

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Riverdale, MD 27037

02-022-58n

1. USDA Reference Number

2. Applicant Reference Number 2002-257XRAB

3. Applicant/Responsible Party

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Phone

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EMail

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Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 20, 2002 - February 20, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Hybrid: Bobwhite

CBI-DELETED

Monsanto Reference ID

2002-257XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2002-257XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

A total of 3000 pounds of seed may be shipped for the term of this Notification Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

KS, MO, MT, SD

DESTINATION:

KS, MO, MT, SD

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID
2002-257XRAB

SD

[CBI Deleted] -- *Spink County/Province, SD, USA

[CBI Deleted] -- *Minnehaha County/Province, SD, USA

[CBI Deleted] -- *Brookings County/Province, SD, U.S.A

[CBI Deleted] -- *Brookings County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID
2002-257XRAB

[CBI Deleted] -- *Codington County/Province, SD, USA

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID
2002-257XRAB

SD

[CBI Deleted] -- *Spink County/Province, SD, USA

[CBI Deleted] -- *Minnehaha County/Province, SD, USA

[CBI Deleted] -- *Brookings County/Province, SD, U.S.A

CBI-DELETED

Monsanto Reference ID
2002-257XRAB

[CBI Deleted] -- *Brookings County/Province, SD, USA

[CBI Deleted] -- *Codington County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID

2002-257XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (2)

SD

[CBI Deleted] -- Spink County/Province, SD, USA, 5 acres

[CBI Deleted] -- Codington County/Province, SD, USA, 5 acres

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CBI-DELETED

MONSANTO COMPANY

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FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2002-257XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

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Permit Unit

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02-022-58n

1. USDA Reference Number

2. Applicant Reference Number 2002-257XRAB

3. Applicant/Responsible Party

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Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C);monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 20, 2002 - February 20, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Hybrid: Bobwhite

Monsanto Reference ID

2002-257XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID

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7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 3000 pounds of seed may be shipped for the term of this Notification Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

KS, MO, MT, SD

DESTINATION:

KS, MO, MT, SD

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

Monsanto Reference ID

2002-257XRAB

SD

[CBI Deleted] -- *Spink County/Province, SD, USA

[CBI Deleted] -- *Minnehaha County/Province, SD, USA

[CBI Deleted] -- *Brookings County/Province, SD, U.S.A

[CBI Deleted] -- *Brookings County/Province, SD, USA

Monsanto Reference ID
2002-257XRAB

[CBI Deleted] -- *Codington County/Province, SD, USA

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

Monsanto Reference ID
2002-257XRAB

SD

[CBI Deleted] -- *Spink County/Province, SD, USA

[CBI Deleted] -- *Minnehaha County/Province, SD, USA

[CBI Deleted] -- *Brookings County/Province, SD, U.S.A

Monsanto Reference ID
2002-257XRAB

[CBI Deleted] -- *Brookings County/Province, SD, USA

[CBI Deleted] -- *Codington County/Province, SD, USA

Monsanto Reference ID

2002-257XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (2)

SD

[CBI Deleted] -- Spink County/Province, SD, USA, 5 acres

[CBI Deleted] -- Codington County/Province, SD, USA, 5 acres

MONSANTO



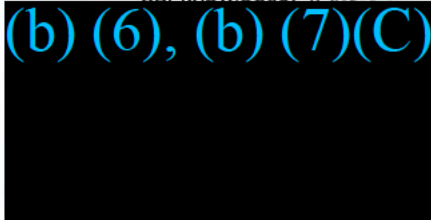
MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID
2002-257XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 30, 2002

Dear Mr. Sim IV:

Enclosed is notification 02-022-58n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-58n	Applicant #:	2002-257XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_009053

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 30, 2002

Dear Mr. Brown:

Enclosed is notification 02-022-58n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-58n	Applicant #:	2002-257XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_009054

file copy

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 30, 2002

Dear Mr. Ames:

Enclosed is notification 02-022-58n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-58n	Applicant #:	2002-257XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

JS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_009055

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

January 30, 2002

Dear Mr. Fridley:

Enclosed is notification 02-022-58n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-58n	Applicant #:	2002-257XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_009056



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 30, 2002

Dear Mr. Brown:

Enclosed is notification 02-022-58n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-58n	Applicant #:	2002-257XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Michael E. Brown

Signature:

(b) (6), (b) (7)(C)

Date:

02/15/02

State:

MO

Rptloc01/R4



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OR120018_BR_009057

FEB 20 2002



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Gregory H. Ames, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 30, 2002

Dear Mr. Ames:

Enclosed is notification 02-022-58n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-58n	Applicant #:	2002-257XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

✓

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 2/7/02

State: Montana

Rptloc01/R4



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OR120018_BR_009058

FEB 7 2002



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

January 30, 2002



Dear Mr. Fridley:

Enclosed is notification 02-022-58n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-022-58n Applicant #: 2002-257XRAB
Received: January 22, 2002 Effective: February 21, 2002
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MO MT SD
Release destination: SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature:

(b) (6), (b) (7)(C)

Date: 2/11/02

State: South Dakota

Rptloc01/R4



APHIS, Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_009059

FEB 14 2002

February 21, 2002

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 21, 2002.

Interstate movement and Release

Notification no. 02-022-58n (2002-257XRAB)

Regulated article - Wheat

Destinations - Kansas, Missouri, Montana, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

JS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Ames, Montana Dept. of Agric., Helena, MT
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
File number 02-022-58n

OR120018_BR_009060

Confirmation Report-Memory Send

Time : Feb-26-02 11:00am
Tel line 1 :
Tel line 2 :
Name :

Job number : 504
Date : Feb-26 10:59am
To : 916367377085
Document Pages : 01
Start time : Feb-26 10:59am
End time : Feb-26 11:00am
Pages sent : 01
Job number : 504

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Permits &
Risk
Assessments

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

February 21, 2002

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 21, 2002.

Interstate movement and Release
Notification no. 02-022-58a (2002-257XRAB)
Regulated article - Wheat
Destinations - Kansas, Missouri, Montana, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Ames, Montana Dept. of Agric., Helena, MT
K. Fridley, South Dakota Dept. of Agric., Pierre, SD



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An Equal Opportunity Employer

OR120018_BR_009061

CONFIDENTIAL

2002 Wheat Field Test Report
USDA #02-022-58n **Monsanto #2002-257XRAB**

August 8, 2003

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147308028	Spink	SD
2147303325	Codington	SD

Spink County/SD (2147308028)

(b) (4)

(b) (4)

Codington County/SD (2147303325)

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2002 Wheat Field Test Report
USDA #02-022-58n Monsanto #2002-257XRAB

August 8, 2003

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147308028	Spink	SD
2147303325	Codington	SD

Spink County/SD (2147308028)

Planting Date: 04/17/2002

Harvest Date: 07/31/2002

Destruct Date: 08/01/2002

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Codington County/SD (2147303325)

Planting Date: 04/23/2002

Harvest Date: 08/13/2002

Destruct Date: 08/13/2002

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

1/30/02 8:23 am

Notification Tracking Sheet

=====
Bp number: 02-022-59n
=====

App number: 2002-258XRAB
Received: 1/22/02
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/21/02
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: **(b) (6), (b) (7)(C)**
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: **(b) (6), (b) (7)(C)**
Begin movement: 2/20/02
End movement: 2/20/03
Begin release: 2/20/02
End release: 2/20/03
Acre: 10.00
CBI status: CBI
Fax: 636-737-7085
=====

- | | Initial | Date |
|--|------------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>apl</i>] | [1/30/02] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>hryp</i>]* | [1/31/02]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>Kxro</i>] | [2/6/02]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*	KS	*SCR *
Interstate	*Dest*	MN	*NER *
Interstate	*Dest*	MO	*SCR *
Interstate	*Dest*	ND	*SCR *
Interstate	*Dest*	SD	*SCR *
Interstate	*Orig*	KS	*SCR *
Interstate	*Orig*	MN	*NER *
Interstate	*Orig*	MO	*SCR *
Interstate	*Orig*	ND	*SCR *
Interstate	*Orig*	SD	*SCR *
Release	*	MN	* 1*NER *

- | | | |
|--|-----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>apl</i>] | [1/31/02] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>Kxro</i>] | [3/15/02]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>Kxro</i>] | [3/20/02] |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify | | |

OR120018_BR_009068

7

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2002-258XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-022-59n

1. USDA Reference Number

2. Applicant Reference Number 2002-258XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 20, 2002 - February 20, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Hybrid: Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2002-258XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2002-258XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 3000 pounds of seed may be shipped for the term of this Notification. Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

KS, MN, MO, ND, SD

DESTINATION:

KS, MN, MO, ND, SD

Ship From:

KS

*[(b) (4) Sedgwick County/Province, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C)
USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

MN

*[(b) (4) Ramsey County/Province, MN,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

*[(b) (4) Polk County/Province, MN, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2002-258XRAB

*[(b) (4) Ramsey County/Province, MN,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b) (4) St. Louis County/Province, MO (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)
USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

ND

*[(b) (4) Cass County/Province, ND, (b) (4) USA

CONTACT: (b) (4) ND (b) (4) USA,
(b) (4)

] - CBI

SD

*[(b) (4) Brookings County/Province, SD,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2002-258XRAB

Ship To:

KS

*[(b) (4)] Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MN

*[(b) (4)] Ramsey County/Province, MN,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4)] Polk County/Province, MN, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4)] Ramsey County/Province, MN,
(b) (4) USA

CONFIDENTIAL

Monsanto Reference ID
2002-258XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C)
MN (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

MO

*(b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
USA (b) (4), (b) (6), (b) (7)(C) MO (b) (4), (b) (6), (b) (7)(C)

] - CBI

ND

*(b) (4) Cass County/Province, ND (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

SD

*(b) (4) Brookings County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2002-258XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (1)

MN

(b) (4) Polk County/Province, MN, U.S.A., 10
acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

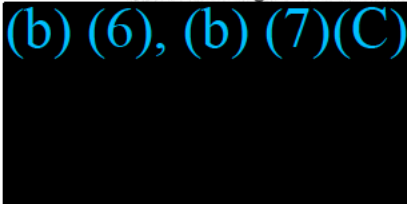
Monsanto Reference ID

2002-258XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector componets) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Citric Acid v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2002-258XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-022-59n

1. USDA Reference Number

2. Applicant Reference Number 2002-258XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 20, 2002 - February 20, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Hybrid: Bobwhite

CBI-DELETED

Monsanto Reference ID

2002-258XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2002-258XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

A total of 3000 pounds of seed may be shipped for the term of this Notification. Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

KS, MN, MO, ND, SD

DESTINATION:

KS, MN, MO, ND, SD

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MN

[CBI Deleted] -- *Ramsey County/Province, MN, USA

[CBI Deleted] -- *Polk County/Province, MN, U.S.A.

CBI-DELETED

Monsanto Reference ID
2002-258XRAB

[CBI Deleted] -- *Ramsey County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, USA

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID
2002-258XRAB

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MN

[CBI Deleted] -- *Ramsey County/Province, MN, USA

[CBI Deleted] -- *Polk County/Province, MN, U.S.A.

[CBI Deleted] -- *Ramsey County/Province, MN, USA

CBI-DELETED

Monsanto Reference ID
2002-258XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, USA

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID

2002-258XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (1)

MN

[CBI Deleted] -- Polk County/Province, MN, U.S.A., 10 acres

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

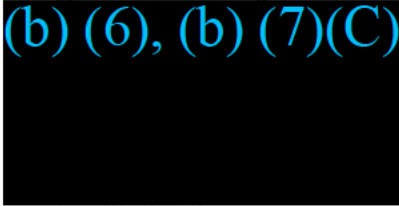
Monsanto Reference ID

2002-258XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

MONSANTO



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CS-DELETED

Monsanto Reference ID

2002-258XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-022-59n

1. USDA Reference Number

2. Applicant Reference Number 2002-258XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 20, 2002 - February 20, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Lines derived from Cultivar/Hybrid: Bobwhite

Monsanto Reference ID

2002-258XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID

2002-258XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

A total of 3000 pounds of seed may be shipped for the term of this Notification. Ship up to 1000 pounds wheat seed to and from each location.

ORIGIN:

KS, MN, MO, ND, SD

DESTINATION:

KS, MN, MO, ND, SD

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MN

[CBI Deleted] -- *Ramsey County/Province, MN, USA

[CBI Deleted] -- *Polk County/Province, MN, U.S.A.

Monsanto Reference ID
2002-258XRAB

[CBI Deleted] -- *Ramsey County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, USA

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

Monsanto Reference ID
2002-258XRAB

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MN

[CBI Deleted] -- *Ramsey County/Province, MN, USA

[CBI Deleted] -- *Polk County/Province, MN, U.S.A.

[CBI Deleted] -- *Ramsey County/Province, MN, USA

Monsanto Reference ID
2002-258XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, USA

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

Monsanto Reference ID

2002-258XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (1)

MN

[CBI Deleted] -- Polk County/Province, MN, U.S.A., 10 acres

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

(b) (6), (b) (7)(C)

Monsanto Reference ID
2002-258XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 30, 2002

Dear Mr. Sim IV:

Enclosed is notification 02-022-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-022-59n Applicant #: 2002-258XRAB
Received: January 22, 2002 Effective: February 21, 2002
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO ND SD
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_009096

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

January 30, 2002

Dear Dr. Hanks: _____

Enclosed is notification 02-022-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-59n	Applicant #:	2002-258XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO ND SD		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_009097

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 30, 2002

Dear Mr. Brown:

Enclosed is notification 02-022-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-59n	Applicant #:	2002-258XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO ND SD		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_009098

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

January 30, 2002

Dear Mr. Nelson:

Enclosed is notification 02-022-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-59n	Applicant #:	2002-258XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO ND SD		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

181

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_009099

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

January 30, 2002

Dear Mr. Fridley:

Enclosed is notification 02-022-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-59n	Applicant #:	2002-258XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO ND SD		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_009100



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

January 30, 2002

Dear Dr. Hanks:

Enclosed is notification 02-022-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-022-59n Applicant #: 2002-258XRAB
Received: January 22, 2002 Effective: February 21, 2002
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO ND SD
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination, *with the attached additional condition 5*

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: *Mary J. Hanks*

Signature: (b) (6), (b) (7)(C)

Date: *3-8-02*

State: *MN*

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 30, 2002

Dear Mr. Brown:

Enclosed is notification 02-022-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-59n	Applicant #:	2002-258XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO ND SD		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

 X State concurs with APHIS determination.

 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 02/15/02

State: MO

Rptloc01/R4



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An Equal Opportunity Employer

FEB 20 2002

OR120018_BR_009102



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

release

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

January 30, 2002

Dear Mr. Nelson:

Enclosed is notification 02-022-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-022-59n Applicant #: 2002-256XRAB
Received: January 22, 2002 Effective: February 21, 2002
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO ND SD
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

in attached continuation

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: *Dr. D. Nelson*

Signature: (b) (6), (b) (7)(C)

Date: *2-28-02*

State: *ND*

Rpt.loc01/R4



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An Equal Opportunity Employer

MAR 15 2002

OR120018_BR_009103

AGRICULTURE COMMISSIONER
ROGER JOHNSON



PHONE (701) 328-2231
(800) 242-7535
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE
State of North Dakota
600 E. Boulevard Ave. Dept. 602
Bismarck, ND 58505-0020

TO: Mary Jackson
Biotechnology Program Operations – Permit Unit
USDA APHIS
4700 River Road
Riverdale MD 27037

FROM: David R. Nelson

(b) (6), (b) (7)(C)

DATE: March 27, 2002

RE: Modification of Conditions for Release of Wheat
02-022-59n
02-051-19n
02-046-30n
02-022-57n

Following further discussions with Monsanto we are making a slight modification in the conditions for release of the wheat notifications listed above.

North Dakota Supplemental Conditions 2002

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.

2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.

3. Because of the possibility of volunteers:

- Wheat should not be grown within the field trial area nor within 33 feet of the field trial area during the subsequent growing season and any wheat volunteers appearing within this area should be destroyed prior to flowering.

-If wheat grown for harvest as grain is grown within 330 feet of the field trial during the year of the field trial, then wheat intended for use as seed should not be grown within this area during the following year.

cc (b) (6), (b) (7)(C) Monsanto

OR120018_BR_009104



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182



January 30, 2002

Dear Mr. Fridley:

Enclosed is notification 02-022-59n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-59n	Applicant #:	2002-258XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO ND SD		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 2/11/02

State: South Dakota

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_009105

FEB 14 2002

March 15, 2002

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 15, 2002.

Interstate movement and Release

Notification no. 02-022-59n (2002-258XRAB)

Regulated article - Wheat

Destinations - Kansas, Minnesota, Missouri, North Dakota, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota concurs with APHIS determination, with (attached) amended additional conditions.

In addition, the State of North Dakota has (attached) modification of conditions for release of wheat.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

81

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
File number 02-022-59n

OR120018_BR_009106

AGRICULTURE COMMISSIONER
ROGER JOHNSON



PHONE (701) 328-2231
(800) 242-7535
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE
State of North Dakota
600 E. Boulevard Ave. Dept. 602
Bismarck, ND 58505-0020

TO: Mary Jackson
Biotechnology Program Operations – Permit Unit
USDA APHIS
4700 River Road
Riverdale MD 27037
FROM: David R. Nelson
DATE: March 27, 2002
RE: Modification of Conditions for Release of Wheat
02-022-59n
02-051-19n
02-046-30n
02-022-57n

(b) (6), (b) (7)(C)

Following further discussions with Monsanto we are making a slight modification in the conditions for release of the wheat notifications listed above.

North Dakota Supplemental Conditions 2002

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
3. Because of the possibility of volunteers:
 - Wheat should not be grown within the field trial area nor within 33 feet of the field trial area during the subsequent growing season and any wheat volunteers appearing within this area should be destroyed prior to flowering.
 - If wheat grown for harvest as grain is grown within 330 feet of the field trial during the year of the field trial, then wheat intended for use as seed should not be grown within this area during the following year.

cc (b) (6), (b) (7)(C) Monsanto

OR120018_BR_009107



Minnesota Department of Agriculture

(651) 296-1277

March 25, 2002

Ms. Mary Jackson
Biotechnology Program Operations
Permit Unit
USDA APHIS
4700 River Road
Riverdale, MD 27037

RE: **AMENDED** Additional Conditions for Release of Wheat 02-022-59n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

If the regulated material (wheat) is to be allowed to flower, the

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain entering commercial grain markets must be at least 100 feet.
3. Because of the possibility of volunteers:
 - Wheat should not be grown within the field trial area nor within 10 feet of the field trial area during the subsequent growing season and any wheat volunteers appearing within this area should be destroyed prior to flowering.
 - If wheat grown for harvest as grain is grown within 330 feet of the field trial during the year of the field trial, then wheat intended for use as seed should not be grown within this area during the following year.

These conditions are in addition to those contained in the applicants "Wheat Field Release Performance Standards" as revised January 2002.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial both during the year of the field trial and subsequent years.

Sincerely,

(b) (6), (b) (7)(C)

Mary J. Flanks, Ph.D.
State Biotechnologist

OR120018 BR 009108



Minnesota Department of Agriculture (651) 296-1277

March 8, 2002

Ms. Mary Jackson
Biotechnology Program Operations
Permit Unit
USDA APHIS
4700 River Road
Riverdale, MD 27037

Fax: 301-734-8910

RE: Additional Conditions for Release of Wheat 02-022-59n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

If the regulated material (wheat) is to be allowed to flower, the

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain entering commercial grain markets must be at least 100 feet.

These conditions are in addition to those contained in the applicants "Wheat Field Release Performance Standards" as revised January 2002.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial.

Sincerely,

(b) (6), (b) (7)(C)

Mary J. Hanks, Ph.D.
State Biotechnologist

AGRICULTURE COMMISSIONER
ROGER JOHNSON



PHONE (701) 328-2231
(800) 242-7535
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE
State of North Dakota
600 B. Boulevard Ave. Dept. 602
Bismarck, ND 58505-0020

TO: Mary Jackson
USDA-APHIS-PPQ
Permits-Biotechnology
4700 River Road
Riverdale MD 20737

FROM: David R. Nelson

(b) (6), (b) (7)(C)

DATE: February 28, 2002

RE: Bp number 02-022-59n

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat appearing within this area should be destroyed.

OR120018_BR_009110



Minnesota Department of Agriculture

(651) 296-1277

April 12, 2002

Ms. Mary Jackson
Biotechnology Program Operations
Permit Unit
USDA APHIS
4700 River Road
Riverdale, MD 27037

RE: **AMENDMENT** - Additional Conditions for Release of Wheat 02-077-09n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

If the regulated material (wheat) is to be allowed to flower, the

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain entering commercial grain markets must be at least 100 feet.
3. Because of the possibility of volunteers:
 - Wheat should not be grown within the field trial area nor within the 100 ft isolation area around the field trial area during the subsequent season and any wheat volunteers appearing within this area should be destroyed prior to flowering.

These conditions are in addition to those contained in the applicants "Wheat Field Release Performance Standards" as revised January 2002.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial both during the year of the field trial and subsequent years.

Sincerely,

(b) (6), (b) (7)(C)

Mary J. Hanks, Ph.D.
State Biotechnologist



Minnesota Department of Agriculture

(651) 296-1277

April 12, 2002

Ms. Mary Jackson
Biotechnology Program Operations
Permit Unit
USDA APHIS
4700 River Road
Riverdale, MD 27037

RE: **SECOND AMENDMENT** - Additional Conditions for Release of Wheat 02-022-59n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

If the regulated material (wheat) is to be allowed to flower, the

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain entering commercial grain markets must be at least 100 feet.
3. Because of the possibility of volunteers:
 - Wheat should not be grown within the field trial area nor within the 100 ft isolation area around the field trial area during the subsequent season and any wheat volunteers appearing within this area should be destroyed prior to flowering.

These conditions are in addition to those contained in the applicant's "Wheat Field Release Performance Standards" as revised January 2002.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial both during the year of the field trial and subsequent years.

Sincerely,

(b) (6), (b) (7)(C)

Mary J. Hanks, Ph.D.
State Biotechnologist

Confirmation Report-Memory Send

Time : Mar-18-02 06:37pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 019
Date : Mar-18 06:36pm
To : 916367377085
Document Pages : 03
Start time : Mar-18 06:36pm
End time : Mar-18 06:37pm
Pages sent : 03
Job number : 019

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Permits &
Risk
Assessments

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

March 15, 2002

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear

(b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 15, 2002.

Interstate movement and Release
Notification no. 02-022-59n (2002-258XRAB)
Regulated article - Wheat
Destinations - Kansas, Minnesota, Missouri, North Dakota, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota concurs with APHIS determination, with (attached) additional conditions.

In addition, the State of North Dakota has (attached) conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_009113

CONFIDENTIAL

2002 Wheat Field Test Report
USDA #02-022-59n **Monsanto #2002-258XRAB**

September 19, 2003

Biotech Field Compliance Team
Monsanto Company

Location
2147301548

County
Polk

State
MN

Polk County/MN (2147301548)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2002 Wheat Field Test Report
USDA #02-022-59n Monsanto #2002-258XRAB

September 19, 2003

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147301548	Polk	MN

Polk County/MN (2147301548)

Planting Date: 05/03/2002

Harvest Date: 08/07/2002

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]